

**IMPROVING NIH MANAGEMENT  
AND OPERATION:  
A LEGISLATIVE HEARING ON THE  
NIH REFORM ACT OF 2006**

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**HEARING  
BEFORE THE  
COMMITTEE ON ENERGY AND  
COMMERCE  
HOUSE OF REPRESENTATIVES**

**ONE HUNDRED NINTH CONGRESS  
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# **IMPROVING NIH MANAGEMENT AND OPERATION: A LEGISLATIVE HEARING ON THE NIH REFORM ACT OF 2006**

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**TUESDAY, SEPTEMBER 19, 2006**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The committee met, pursuant to notice at 2:08 p.m., in Room 2123 of the Rayburn House Office Building, the Hon. Joe Barton [Chairman] presiding.

Members Present: Representatives Barton, Upton, Deal, Norwood, Shimkus, Terry, Rogers, Murphy, Burgess, Blackburn, Dingell, Waxman, Rush, Stupak, Engel, Wynn, Green, and Doyle.

Staff Present: Katherine Martin, Counsel; Ryan Long, Counsel; Brandon Clark, Policy Coordinator; Chad Grant, Legislative Clerk; John Ford, Minority Counsel; and Jessica McNiece, Minority Research Assistant.

CHAIRMAN BARTON. The hearing will come to order.

I want to thank our witnesses for being here today to testify about the importance of reauthorizing the National Institutes of Health. We are going to hear from a variety of individuals today, including the current director, Dr. Zerhouni. I want to particularly thank Dr. Zerhouni for his patience and his generous assistance in providing much-needed feedback on the various drafts that we have gone through in the last several years, his cooperation at the numerous hearings that we have had, and many, many background briefings and meetings that he and I have had on this subject.

I think it is time to reauthorize the NIH. When I became Chairman of this distinguished committee 3 years ago, I made it one of my top priorities to reauthorize this fine institution. I never dreamed it would take 3 years to get to this day. It is a project that is long overdue. It has been 13 years since we had an authorization for the NIH. It was last reauthorized for the fiscal years 1994 through 1996, and as we all know, we are now in the year 2006, and about to go into fiscal year 2007.

During this last decade, science and research have changed dramatically. Congress has recognized that by doubling the budget of the NIH. However, just doubling the money isn't enough. Our job should be to give NIH the tools that it needs to bring accountability,

transparency, and transformational policies into what is now closing in on a \$30 billion research agency.

The NIH that we know today, with the best of intentions, is a hodgepodge of different interests. I anticipate that we are going to hear about some of those interests from our witnesses today. We are also going to hear that they believe, as I believe, that the agency needs to be reorganized and revitalized. The Institute of Medicine recently issued a report calling for a number of new management tools needed at the NIH. Under the direction of Dr. Zerhouni, many of these recommended are currently being implemented, or at least being studied under his roadmap initiative.

I think it is incumbent on us as members of the authorizing committee to codify these changes into Federal law, and also add to the functional organizational structure of the agency.

The NIH has a very big job. It has a great deal of money to do that job, and I support both the agency and its mission. I want to reiterate that. I support the agency of NIH and I support its mission. It, literally, is one of the crown jewels of the Federal Government.

I do believe, however, that the NIH can do better and it can do its part by reporting back to Congress and the public, who provide the funding through tax dollars, on how that money is being spent. We hear a lot about lack of new funding at the NIH. I think that that is a problem, but we don't have enough transparency. We don't have the systems in place right now, in my opinion, to really determine the best uses to put new money, and perhaps even some of the current funds that are being spent at the NIH.

We have drafted legislation. I can't tell you the exact number of drafts that we have had, but we have had more than one draft over the last several years, which we have sent out to the stakeholders for their review. We have looked at these drafts legislatively on a bipartisan basis, staff members and members of the committee, trying to get exactly the right mix on what we need to do to change things at NIH. The stakeholder community, including the entirety of the representatives of our first panel, reacted to our very first draft with a number of concerns, suggestions--some praise, but very little praise.

We have listened and over the course of the past year we have worked and reworked various drafts with the stakeholder community as well as directors at the NIH to ensure that the bill that we hope to mark up tomorrow is as good a product as it is possible to have.

I believe that while no bill is perfect, the bill that is before us today in draft form is a very, very good bill. The response to this latest draft has been overwhelmingly positive. The bill has received widespread endorsement from disease advocacy groups, patient advocacy groups,

universities, medical colleges, researchers, scientists, the list goes on. After 13 years, we finally have legislation that apparently is getting it right. I am going to work very hard at the last stage of this Congress to make this bill law or this bill, with some modifications, if it is the wisdom of this committee and others in the other body to make some minor changes, to help the NIH move forward into the 21st Century with the organization, the management and the funding that it needs to keep people healthy.

I want to commend my Ranking Member, Mr. Dingell. He and his staff have worked hand in glove for the last 2 years providing numerous suggestions, numerous alternatives, and when necessary, positive constructive criticism of changes that need to be made.

It is seldom that the Congress actually does the right thing for the right reasons, but in this case, I think that we are doing the right thing for the right reason. If we can have a successful hearing today and a successful markup tomorrow and get our friends in the other body to work with us, we can put a bill on the President's desk in this Congress. It does revitalize and reform the National Institutes of Health, and I think that is an achievement worth working hard for in the last few weeks of this Congress.

With that, I am going to yield to my distinguished Ranking Member, Mr. Dingell, for any opening statement that he wishes to make.

[Prepared Statement of the Hon. Joe Barton follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY  
AND COMMERCE

Thank you to all our witnesses today for testifying before our Committee on the importance of reauthorizing the National Institutes of Health. Today we are hearing from a variety of witnesses who are involved with the NIH. I would particularly like to recognize Dr. Zerhouni for the patience and generous assistance he has provided through the numerous hearings and countless meetings on this subject during my Chairmanship.

It's time for us to do our job and reauthorize the National Institutes of Health. When I became Chairman of this Committee one of my first priorities was to reauthorize the NIH. It was a project long overdue then, and now 13 years have passed since the agency was last authorized. Within this time, science and research have changed dramatically and Congress recognized that by doubling the budget of NIH. Just spending double the money on research isn't enough, however. Our job is to give NIH the tools it needs to bring the real accountability and transparency needed to efficiently run a \$30 billion agency.

The NIH that all of us know is a hodge-podge of different interests. I anticipate we will hear from our witnesses that the agency is in desperate need of organization. The Institute of Medicine recently issued a report calling for a number of new management tools needed by the NIH. Under the astute direction of Dr. Zerhouni, many of these recommendations are currently being implemented under the roadmap initiative. It is now incumbent upon us as members of the authorizing committee to codify these changes as well as add to the functional organization of the agency.

NIH has a big job and a great deal of money to do it, and I strongly support both the agency and its mission. I do, however, believe that NIH needs to do its part by reporting back to Congress and the public who provide the funding through tax dollars on how the money is being spent. We hear a lot about a lack of funding or the need for programs, but with so little transparency in the NIH, we cannot properly respond to their concerns.

This Committee released draft legislation over a year ago proposing changes to the NIH. The stakeholder community, including the entirety of our first panel, reacted to that draft with a number of concerns, suggestions, and some praise. Over the course of the past year, I have worked with the community as well as the NIH to ensure that the bill we are marking up tomorrow is as good a product as we can have. I believe that this goal has been achieved.

The response has been overwhelmingly positive. The bill has received widespread endorsement from disease advocacy groups, patient advocacy groups, universities, medical colleges, researchers, scientists, and the list goes on. After thirteen years of inaction we finally have legislation that gets it right. This bill ensures the NIH will move forward in the 21<sup>st</sup> century with the organization, management, and funding it needs to keep people healthy.

MR. DINGELL. Mr. Chairman, I thank you for scheduling the hearing, and I thank you for recognizing me. I very much look forward to the hearing and to the testimony of our witnesses.

Dr. Zerhouni is a fine public servant, and I have great respect for the work he has done as Director of our National Institutes of Health. I am particularly pleased that we have another panel of witnesses who collectively represent a very distinguished level of experience in the area of healthcare and research, and we are fortunate to have them here today. They represent a majority of the people and institutions that do much of the extramural research that is funded by NIH.

And I want to particularly welcome Dr. Kirch, who by most happy and interesting circumstances is Executive Vice President for Medical Affairs, and CEO of the University of Michigan Health Systems. Doctor, welcome to you.

CHAIRMAN BARTON. Did they play in the football game Saturday?

MR. DINGELL. As a matter of fact, and very well, too.

I am also pleased that we will have the benefit of the perspective of a major patient advocacy organization, the American Heart Association.

The legislation that will be discussed today has its roots in the concerns raised by a number of past NIH directors and specifically takes into account several recommendations included in the Institute of Medicine report entitled "Enhancing the Vitality of the National Institutes of Health, Organizational Change to Meet New Challenges." This legislation has been developed in consultation not only with the stakeholders, but with the committee democratic staff, and I want to express my appreciation to you, Mr. Chairman, for that.

Mr. Chairman, you have made the reauthorization of NIH one of your priorities as Chairman of the committee, and appropriately so,



because in my view, NIH is one of the crown jewels under this committee's jurisdiction. And it has been more than 13 years, as you have observed, since we moved any legislation of this kind.

I believe you have proceeded in a manner that shows your appreciation for the seriousness of this task, and I want to commend you for your leadership and the vigor in which you have addressed it. I do find, and I regret this, Mr. Chairman, the ability of our members to review this language at this point in the session with the care that it really requires is going to be limited, because subcommittee consideration is being skipped altogether, and we are now moving to markup in the full committee tomorrow morning.

I find that that is a situation which creates great peril and possibility of misunderstandings, and carries with it the potential for mischief being done to what I regard as not only a fine effort by you, Mr. Chairman, but also a real necessary piece of legislation.

I wish we had more time to address this under a less limited process, and I think that more time could be achieved. I will say that the shortage of time and the difficulty of proceeding under the stringent circumstances of the kind of proceedings that we proceed under poses risk to the legislation and I think threatens your efforts to do something which are indeed very important.

I will remain anxious to be of assistance to you. I will observe that the substance of the bill in my view is good. I do remain concerned about the adequacy of funding levels, however.

The bill has garnered broad support in the stakeholder community, and that fact isn't more than a little comfort to me. When tomorrow's markup occurs, I will be listening to my colleagues and concerns that they would have of this bill.

Mr. Chairman, I want to commend you again for embarking upon the, what I know is a very important and difficult task. I know that you have tried to address the concerns, but I do note that other concerns remain outstanding.

Again, Mr. Chairman, I thank you, and I look forward to the testimony of our distinguished witnesses.

CHAIRMAN BARTON. We thank the gentleman from Michigan and recognize the gentleman from Georgia.

MR. NORWOOD. Thank you very much, Mr. Chairman. I will be brief and submit most of my remarks for the record, but I would like to thank you and congratulate you on bringing this bill forward. I know how hard you have worked on this, how important it is to you, and, in fact, to all of this committee; 13 years is a long time, and it is very much time that we got this done. And it seems at least at this point that there is great consensus on what your work has been.

I also want to welcome Dr. Kirch; he is a former dean at the Medical College of Georgia. I am glad to see you out here today. And thank you and all of you for your testimony.

And lastly, I think it is always appropriate for us to thank Dr. Zerhouni, because of his difficult and hard work and great leadership over at NIH; we thank him once again for appearing before our panel.

With that, Mr. Chairman, I will ask the rest be placed in the record.

CHAIRMAN BARTON. Without objection, so ordered.

The distinguished gentleman from California, Mr. Waxman, is recognized for an opening statement.

MR. WAXMAN. Mr. Chairman, I welcome the hearing today on the proposals recently put forward by you to reauthorize and reorganize NIH.

We are dealing with one of the most pre-eminent health agencies of the Federal Government, recognized for its fine work here and around the world.

All Members of Congress and most Americans believe that the NIH is the crown jewel of government funding, it is an agency that we are all very proud of. Mr. Barton has worked hard to secure support for the changes he is interested in making. He has substantially moderated his proposal from last year; it is clearly better, and I think the views on the proposal that we will hear from witnesses today reflect that.

But we are, I think, in a situation where we are dealing with an agency that is not broken. We ought to proceed with caution and be sure that what we do improves its function. We are still making substantial changes in the NIH that many in the research and patient community have had little time or opportunity to review and fully understand. This bill I think in its final form was introduced last week, we are holding our hearing today, we are marking it up tomorrow, it is going to the House floor very soon, and the Chairman said he would like the Senate to pass it before we leave, which is 2 or 3 weeks from now, or maybe when we come back for the lame duck session.

Is it fully understood, for example, that under this bill, the institutes and centers of the NIH will be authorized at a level below the traditional levels of the biomedical research development price index. Even if the 5 percent is fully appropriated, with half reserved for the Common Fund, there will not be enough funds to cover inflation for our research institutes. I understand there will be an amendment to try to increase that funding.

Is it fully understood--it is not in the bill now--that the Director of the NIH is given the power to eliminate institutes and centers established by law after a hearing process and 90-day notification to the Congress? Do people really understand that offices like the Office of Women's

Health and the Office of AIDS Research, also established by law, could be eliminated without Congressional notification? In each case, Congress can stop this only by legislation that will have to be subject to a Presidential veto.

Further, a Science Management Board could effectuate the same changes, removing the process from public accountability. This runs contrary to my own basic view that this is the business of the Congress. Recommend changes to us? Yes. But Congress is the one that should act, and I believe, in fact, this is very much what the Institute of Medicine study said, which gave a lot of impetus to this legislation.

I raise these points partly because they reflect my deep concerns with the bill, and partly to demonstrate that we move ahead with a full understanding of the impact of the legislation.

I look forward to hearing from the witnesses today. Thank you, Mr. Chairman.

CHAIRMAN BARTON. We thank the gentleman.

The gentleman from Illinois, Mr. Shimkus.

MR. SHIMKUS. Thank you, Mr. Chairman. I appreciate your effort to move this forward. And I want to thank the panelists for coming. And this is a time to see what is in the bill, to say what is good and raise some concerns, and then we will move forward.

I appreciate, Mr. Chairman, the issue of the Common Fund and the NIH issue because a lot of the research, as we know, works cross purposes, and I think that is a very--instead of staying in stovepiped areas, that the communication across fields, the more you get involved in this, the better it will help all research, and that is a very positive change.

I also appreciate in section 5 on the report, having rehabilitation services included in that what type of benefits that occurs to the whole body of health. And I appreciate this hearing and look forward to moving forward, and I yield back my time, Mr. Chairman.

CHAIRMAN BARTON. I thank the gentleman.

The other gentleman from Illinois, Mr. Rush, is recognized for 3 minutes.

MR. RUSH. Thank you, Mr. Chairman, for recognizing me. And I want to thank our panelists for being here today, and I also want to commend you on having this hearing.

Mr. Chairman, as we proceed to full committee markup of a comprehensive reauthorization of the National Institutes of Health, my chief concern is the same as it was in previous hearings on NIH. I am concerned that the committee print before us does not do enough to address the persistent evil of racial health disparities that continues to plague our Nation.

I do not find anything objectionable to the committee print itself, and I think it is a good piece of bipartisan cooperation that creates accountability and ensures the vitality of the greatest research institution in the world. However, because I regard health disparities as one of the most blatant enduring injustices in our country today, I simply cannot ignore the fact that the legislation is silent on this issue. I believe that we should be doing more to address health disparities, particularly among minorities at NIH; indeed, the Institute of Medicine declared likewise in its comprehensive study on NIH.

Mr. Chairman, this is not merely a special interest issue whereby I am advocating specific research on one area over another. I appreciate your desire to avoid a disease battle or an institute war when members of this committee start favoring one illness over another or one institute over another. And I agree with you, Mr. Chairman, I don't want this bill to become bogged down in special interests, but addressing health disparity isn't about that, it is about tackling a chronic social problem, ensuring a fundamental commitment to basic justice.

Racial health disparities is not a specific biological disease, but a much larger political and social disease that cuts across a whole range of research issues. The proposed legislation is called the NIH Reform Act of 2006. I think, Mr. Chairman, that if we are going to reform NIH, we must reform the organizational impediments and attitudes that perpetrate the racial inequality in medical research.

Mr. Chairman, I look forward to our panelists' testimony, and I yield back the balance of my time.

CHAIRMAN BARTON. I thank the gentleman.

We are aware of some of Mr. Rush's concerns and are working with your staff to try to address those in a manager's amendment. I think you are aware of that. So we are still listening and still trying to work on some of those issues that you have just raised.

Does the distinguished gentleman from Pennsylvania, Dr. Murphy, wish to make an opening statement?

MR. MURPHY. Yes. Thank you, Mr. Chairman.

I am pleased you are moving forward with this bill, it is very important. I know it has been a long time coming. And perhaps the good news that comes with this is not only that it is moving forward now, but also that we have learned so much in the last 2 years about healthcare as well. Some of my interests--actually, the committee's interest and yours as well--are on making sure that we look at not only how things are done in the laboratory or with any disease research, but also how they work together.

My assumption is the Common Fund, which is set up here, will work on integrating and coordinating a lot of that care together, but in

particular, some ways that I see as very, very important that I am hoping final drafts of this legislation include are knowledge of what needs to be done with patient safety, on many, many levels of what hospital and primary and secondary care can do for patients as we look at those issues of patient safety from infections to some of the other things we have dealt with in this committee, but also the issue of integrating care, and that each institute is not a separate entity.

And when you look at things, for example, the Institute of Mental Health can combine with some of the other areas, and we recognize the impact that mental illness has upon cancer and diabetes. And I am hoping that this is an area that we see more growth and research as scientists work together more in collaboration to give us answers on how we can deal with these diseases by coordinating these researches together. So I am pleased that this bill is moving forward, and I look forward to the rest of this hearing.

Thank you, Mr. Chairman.

CHAIRMAN BARTON. I thank the gentleman.

I recognize the distinguished Ranking Member of the Oversight Subcommittee from Michigan who has done excellent work on oversight of NIH, Mr. Stupak, for an opening statement.

MR. STUPAK. Thank you, Mr. Chairman, and thank you for the kind comments. Thanks for holding this hearing. I am going to be in and out, but I am going to come back during questioning because I do have a couple of questions.

I want to thank the Chairman and his willingness to work with our office to include two provisions in the Reauthorization Act. The first one pertains to our Oversight and Investigation hearings concerning the NIH human tissue issue and the language that would require NIH to report to Congress on the progress of their tracking system for human tissue samples. The second issue relates to [clinicaltrials.gov](http://clinicaltrials.gov), where any language that would require NIH to report to the FDA yearly all drug trials added to [clinicaltrials.gov](http://clinicaltrials.gov) website. I believe this is a step in the right direction for drug safety.

However, I believe NIH still has much to do and much progress needs to be made in the area of conflicts of interest in the Public Health Service Corps. Unfortunately, this reauthorization does not allow us to address these issues. In the Oversight and Investigations Subcommittee, we have been addressing it for over the last 4 years, and hopefully we can come to some conclusion and get some strong language in for conflicts of interest, especially with the Public Service Corps.

So I look forward to hearing from our witnesses. I look forward to continuing to work with the committee and the Chairman. And with that, I will yield back, Mr. Chairman. Thank you.

CHAIRMAN BARTON. We thank the gentleman.

The distinguished doctor from Denton, Texas, Dr. Burgess is recognized for an opening statement.

MR. BURGESS. Thank you, Mr. Chairman. And let me add my name to the long list of people who are offering you congratulations for bringing this bill to the floor--to the committee. You should be lauded for proposing important improvements in how the National Institutes of Health operates and prioritizes essential medical research.

I have taken the option of making several field trips to the NIH in my 3 ½ years in Congress, and I just can't tell you how much I am impressed by the researchers, the Institute directors and the overall work that is happening at the National Institutes of Health. It is truly the crown jewel of the Federal government, and we should all be proud of the organization's dedication to improving the health of Americans and mankind.

I think Dr. Zerhouni shared with me a slide when I first went out there that showed 800,000 people between the 1960s and now have not died prematurely from heart disease, largely because of work done at the NIH; that is an outstanding effort.

Advances in cancer care or a greater understanding of the human genome--the NIH has a proven record of innovation. I believe that the bill before us represents important improvements to achieve the numerous missions that the NIH has undertaken. Creation of the Common Fund is especially important to address diseases and public health threats that may not fit neatly into one single institute's portfolio.

The Scientific Management Review Group is also an important component designed to evaluate the design of existing institutes and centers. As medical research of the practice of medicine evolves, it is important that the NIH is an agile and responsive organization. The Review Group will provide an important internal accountability at NIH that is subject to the scientific realities and not decisions based on politics.

I would also add my voice to that of Mr. Rush from Illinois about the needed work to be done on healthcare disparities in this country, it is not unique to any one geographic location in the country and affects my area of north Texas just as severely as it affects Mr. Rush's area of Illinois.

But all and all, this is a good bill. By increasing the organization level, the Energy and Commerce Committee has produced a bipartisan approach to capitalizing on the gains made by the NIH over the last several years.

Mr. Chairman, I yield back.

CHAIRMAN BARTON. I thank the gentleman.

The gentleman from New York City, Mr. Engel, is recognized for an opening statement.

MR. ENGEL. Thank you very much, Mr. Chairman. And I want to thank you for holding this very important hearing on the reauthorization of the National Institutes of Health.

There are few agencies in the United States government that offer as much promise for the future as the NIH. It is important that we strengthen this institution so that it can be better at pursuing advance research to truly improve health services.

I want to personally commend you, Mr. Chairman, and your staff for your willingness to accept changes and revisions suggested by the many stakeholders who work with the NIH. I know that there was considerable concern about many of the provisions in last year's draft, and I know that many if not all of these issues were resolved. While I appreciate that reauthorization for appropriations has been set at 5 percent per year, it is worth noting that the appropriators routinely flat fund NIH. It is obviously disgraceful, and it is important that this committee strongly signal to our friends on Appropriations that 5 percent growth per year should, if anything, be a minimum, be a floor.

Many groups like the Elizabeth Glaser Pediatrics AIDS Foundation and Foundation for AIDS Research believe that the authorization should be much higher, as do I. We could all benefit if more money were in this bill.

I am pleased that the latest bill has secured the endorsement of so many key stakeholders like the Association of American Medical Colleges, Association of American Universities, and the Federation of American Societies for Experimental Biology.

And finally, I would like to thank you again, Mr. Chairman, and your staff for working with my office to include report language on Charcot Marie Tooth Syndrome. Charcot Marie Tooth Syndrome, or CMT, is the most commonly inherited neurological disorder affecting approximately 150,000 Americans. A better reporting system by NIH on the research they are doing on CMT will strengthen our ability to truly understand and treat this disease.

Again, I wish there was more money in the bill, but I know that you have worked very hard. And again, I want to thank you and appreciate the work that your staff has done with mine. And I yield back, Mr. Chairman.

CHAIRMAN BARTON. Thank you, Mr. Engel.

Does Mr. Rogers wish to make an opening statement?

MR. ROGERS. I do not, Mr. Chairman.

CHAIRMAN BARTON. Down in Texas, we had a democratic primary about 50 years ago that Lyndon Johnson won by 54 votes and he got the

nickname "Landslide Lyndon." We have Mr. Wynn next. He had a little bit of a tussle last week, but he did win, and I want to recognize Landslide Wynn for any opening statement.

MR. WYNN. Well, thank you very much, Mr. Chairman. And, in fact, they are still counting, but we are quite optimistic. And I did take a couple of pages out of Lyndon's book, so if I win, it can be attributed to Texas know-how.

CHAIRMAN BARTON. I hope not. I hope you win fair and square.

MR. WYNN. A win is a win.

MR. GREEN. Mr. Chairman, we just are real organized in Texas, we vote alphabetically.

MR. WYNN. Lyndon Johnson was a great president. Thank you, Mr. Chairman, for your remarks. And thank you and Ranking Member Dingell for holding today's hearing on legislation to reauthorize the National Institutes of Health. NIH is located just outside my district, in fact, in Bethesda, Maryland.

Currently, it is a cumbersome process for stakeholders and researchers--and Congress, even--to identify and pinpoint specific research projects and activities being undertaken across the agency. I think today's draft legislation will create an electronic agency-wide reporting system, which will increase transparency of research activities, accountability of research dollars and coordination of research, and I think these are very laudable goals.

The draft also seems to provide a permanent funding mechanism, the Common Fund, for cross-cutting trans-NIH research identified by the Division of Program Coordination Planning and Strategic Initiatives. However, as a member of the Congressional Black Caucus, I am concerned that these structures may unintentionally undercut the National Center on Minority Health and Health Disparities, which serves as a focal point for planning and coordinating minority health and health disparities in research, truly, a trans-NIH initiative across the NIH.

Under the current structure, the center has insufficient authority to allocate and control funding for trans-NIH research on health disparities. My concern is this legislation may exacerbate this insufficiency. I hope I can work with you to ensure that this center is a key entity for coordinating and funding cross-cutting trans-NIH activities that address health disparities, research and development.

Thank you for your time, I relinquish the balance.

[Prepared statement of the Hon. Albert R. Wynn follows:]



PREPARED STATEMENT OF THE HON. ALBERT R. WYNN, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF MARYLAND

Thank you, Chairman Barton and Ranking Member Dingell for holding today's hearing on Legislation to Reauthorize the National Institutes of Health (NIH). We have a fellow Marylander testifying today, whom I would like to extend a warm welcome: Dr. Edward D. Miller, the Chief Executive Officer of Johns Hopkins Medicine in Baltimore. Thank you and we are glad to have you today.

The NIH, the world's leading biomedical research organization, is located just outside my Congressional district in Bethesda, Maryland. It has been 13 years since the NIH has been reauthorized and I support this committee for bringing a bipartisan piece of legislation before us today. The retiring baby boomer generation will pose a new strain to our healthcare system, making it critical that we fast track research on diabetes, cancer, heart disease, Alzheimer's, and other diseases and disorders.

Currently, it is cumbersome for stakeholders, researchers, and Congress to pinpoint specific research projects and activities being undertaken across the agency. The draft bill, which will be considered during full committee as soon as tomorrow, will increase transparency of research activities, accountability of research dollars, and coordination of research by creating an electronic agency-wide reporting system. Additionally, the draft enacts a number of the Institute of Medicine's (IOM) recommendations designed to reduce repetitive research and maximize strategic coordination and planning.

It also seeks to provide a permanent funding mechanism, the "Common Fund," for crosscutting trans-NIH research identified by the "Division of Program Coordination, Planning and Strategic Initiatives." However, as a member of the Congressional Black Caucus, I am concerned that these structures may unintentionally undercut the National Center on Minority Health and Health Disparities (NCMHD), which serves as the focal point for planning and coordinating minority health and health disparities research – truly a trans-NIH initiative – across the NIH. It is my sincere hope that the "Common Fund" will supplement and not supplant existing and future efforts of the Center.

Under the current structure, the Center has insufficient authority to allocate and control funding for trans-NIH research on health disparities. This legislation may exacerbate this insufficiency. I believe it is certainly time for the National Center on Minority Health and Health Disparities to have stronger oversight and authority in achieving its mission and the mission of the NIH.

I intend to work with my colleagues and the Chairman to ensure that health disparities research and development are a core component of the NIH portfolio and that the Center is the key entity for coordinating and funding these crosscutting trans-NIH activities. Furthermore, once enacted, I hope the Center will be represented within the proposed "Council of Councils," which will review trans-NIH funding proposals and within the proposed "Scientific Management Review Group," which will evaluate the structural design of existing Institutes and Centers and make recommendations for reform. The Center cannot be underfunded or marginalized if we are to make a serious effort at eliminating health disparities. I hope this committee can reassure this Center that its work is truly at the heart of the NIH.

On a positive note, I commend this committee for codifying the current role of the Office of Research on Women's Health in overseeing and coordinating trans-NIH research through the "Division of Program Coordination, Planning, and Strategic Initiatives." The Office of Research on Women's Health ensures that research conducted and supported by the NIH adequately addresses issues regarding women's health.

However, it is disappointing to note that no minority health or women's health advocacy groups are testifying today, nor have I seen any letters of endorsement. I do hope that they will reach out to this committee with comment before tomorrow's markup.

Thank you and I look forward to hearing from today's panelists.

CHAIRMAN BARTON. We thank the gentleman. The gentleman from Texas, Mr. Green, is recognized for an opening statement.

MR. GREEN. Thank you, Mr. Chairman, for holding this hearing on the draft bill reauthorizing NIH. We all know what a priority this bill is for you, and I want to thank you for your willingness to work with the stakeholders and revise the legislative text to create a bill that stakeholders can support.

As with any bill, there are a few provisions in the current draft that could use some clarity. Specifically, I am interested in the Council on Councils established in the bill and want to make sure that its establishment and decision making process are as balanced as possible.

I think my colleagues on the committee would join me in calling NIH one of our crown jewels of our committee's jurisdiction. I thank the chairman for actively exerting the committee's jurisdiction on NIH, and for the opportunity to get the clarification we need to ensure that this bill sets the NIH in the right direction for continued success and scientific achievement.

And again, I want to thank our witnesses for being here today. And Mr. Chairman, I yield back the balance of my time.

CHAIRMAN BARTON. We thank the gentleman for his statement.

Seeing no other members present, the chair asks unanimous consent that all members not present have the requisite number of days to put their opening statements in the record. Without objection, so ordered.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF THE HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF OHIO

Thank you, Mr. Chairman, and thanks to Dr. Zerhouni and our other witnesses for joining us today.

Mr. Chairman, you have worked extremely hard, against formidable odds, to craft a reauthorization bill that helps maximizes the return on our nation's investment in the National Institutes of Health, and I commend your efforts.

Ranking Member Dingell's unwavering support for NIH helps explain its endurance and its success. Our nation owes the gentleman from Michigan a debt of gratitude for NIH, one of many public health institutions that have flourished under his watch.

I also want to commend Cheryl Jaeger, John Ford, and the other dedicated staff from the Majority and Minority who worked on this legislation. They did an exceptional job.

Mr. Chairman, I hope your efforts help re-engage Republican members of Congress whose support for medical research appears to be faltering.

Following the lead of President Bush, Republicans in Congress have taken to passing marginal increases in NIH funding, increases that do not even keep up with inflation.

In fact, after the across-the board- cut in discretionary spending, NIH received an actual budget cut in 2006.

Medical research is a public priority. The President and Republican leadership are treating it as an afterthought. That's got to change.

Key provisions of The NIH Reform Act:

- increase the funding available for interdisciplinary, cross-institute research. This fund is intended to ensure that the “silo” structure of NIH does not inadvertently hinder investment in promising avenues of research.
- create a new detailed reporting system. This new system is intended to enable NIH to better assess the strengths and weaknesses in its allocation of research funding.
- create a process for reevaluating the structure of NIH. This new process is intended to ensure that NIH adapts as medical science evolves.

I support these provisions, but there are risks involved in adopting them. It’s important for each member of the Committee to recognize these risks so that we can respond should they become a reality.

The bill increases funding for cross-institute research by devoting half of any increase in annual NIH funding to the common fund.

The idea that any increase we pass in NIH research will automatically be split in two, with only half going to the 27 institutes and centers, is worth considering.

If we continue to pass anemic increases in NIH funding, then 1) we’re not going to build up the common fund; and 2) nothing from nothing leaves nothing. The Institutes that would have received minimal increases will now receive microscopic ones.

Before supporting bifurcation of annual NIH increases, members of this Committee should decide whether they are willing to back healthy annual increases in NIH funding. I hope it’s a no-brainer.

Transparency has tremendous benefits, but the new reporting system created under this bill could be used to pressure NIH into shifting funding away from basic research, the benefits of which accrue over time and generally out of the spotlight, and toward research perceived as delivering more tangible medical benefits.

The report could be used as a tool by policymakers to micromanage NIH, picking and choosing which research projects should and should not be funded.

Stripped of its autonomy, NIH may be able to help policymakers win popularity contests, but unable to invest in the long-shot project that yields the next major scientific breakthrough.

Policymakers must be careful to use this reporting tool for the good, not for political or ideological purposes.

I support frequent reevaluation of NIH’s structure and operations. Medical science evolves and so should NIH.

But this Committee needs to understand that the bill puts into place a “guilty unless proven innocent” model for restructuring NIH.

Unless the Director of NIH opts to -- and can -- justify to Congress why the restructuring recommendations should not be acted upon, NIH is required to act upon them.

I support that approach -- I think we have all become too complacent about the structure of NIH -- but it carries risk.

This Committee and Congress must keep close tabs on the evaluation process and weigh in if there is any evidence that the path of least resistance is also the path to disaster.

I support each of these key provisions, but again, Congress should recognize that this bill does not let us off the hook. If anything, it magnifies the importance of Congressional oversight, Congressional restraint, and Congressional support. I do not agree with every provision of this bill.

For example, I believe there should be an inflation adjuster in the authorization levels and I do not agree that there should be a statutory prohibition on increasing the number of institutes at NIH. That’s just as arbitrary as prohibiting a reduction in the number of Institutes would be. It’s not good policymaking.

However, I am generally supportive of the Chairman's efforts and hope we can continue to work together to improve the bill.

We now want to hear from our first distinguished panel. We are going to start with Dr. Edward Miller, who is the Chief Executive Officer at Johns Hopkins Medicine in Baltimore, Maryland. We have Dr. Robert Eckel, who is professor of the Department of Physiology and Biophysics at the University of Colorado Health Sciences Center. Dr. Darrell G. Kirch, who is the President, Association of American Medical Colleges. We have Dr. Furcht, who is Board of Directors, the Federation of American Societies for Experimental Biology.

**STATEMENTS OF DR. EDWARD MILLER, CHIEF EXECUTIVE OFFICER, JOHNS HOPKINS MEDICINE; DR. ROBERT ECKEL, PROFESSOR, DEPARTMENT OF PHYSIOLOGY AND BIOPHYSICS, UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER; DR. DARRELL G. KIRCH, PRESIDENT, ASSOCIATION OF AMERICAN MEDICAL COLLEGES; AND DR. LEO FURCHT, BOARD OF DIRECTORS, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY.**

CHAIRMAN BARTON. We welcome all of you gentlemen, and we will start with you, Dr. Miller.

DR. MILLER. Thank you, Mr. Chairman and members of the House committee.

I am Ed Miller. I am the Dean and CEO of Johns Hopkins Medicine, and I thank you for this invitation to speak to you. I especially want to thank Chairman Barton for his persistence in developing draft legislation that recognizes the importance of biomedical research.

We also want long-term solutions and cures for devastating diseases and not mere Band-Aids.

Chairman Barton went the extra mile this summer meeting with me and my colleagues to get our input as this bill started to evolve. It has been a long, hard road, but the draft bill represents a major step forward in providing dollars to keep biomedical research on a fast track. It also will put NIH in a fast track to internal reform so it keeps pace with the way research is conducted today.

Let me start by commending the leaders in Washington for their foresight in doubling the NIH research budget between 1998 and 2003. Many of the dramatic advances in identifying early indicators and causes of disease were the result of well-spent Federal dollars. In recent years, however, there has been a hold down in additional support that is beginning to slow research. At Johns Hopkins, we have annually led the

Nation in NIH research dollars, and we have made significant investments in young investigators to support the Nation's effort to advance science. However, there has been a marked decline in new grants awarded to our School of Medicine. Fewer projects are being funded, and NIH support of our ongoing investigation is being cut.

In fiscal year 2002, the average funding of a new grant was \$142,210 for the School of Medicine. However, in fiscal year 2006, the funding dropped nearly \$50,000 per grant to \$92,683, a 34.8 percent decline.

Hardest hit are the young investigators. I fear we may lose a generation of enthusiastic scientists if they conclude that NIH is out of their reach, and we must not let that happen. The bill's provision for a 5 percent increase in the annual funding is of greatest importance. When I met with the Chairman this summer, we agreed that the traditional walls separating branches of medical sciences need to be demolished. Today, we know it takes a community of scientists from many disciplines to unravel the mysteries of the human body. Let me give you a few examples from Hopkins.

We have created the Institute for Computational Medicine. We are harnessing advances in computational methods to analyze and model disease mechanisms so that we can understand how diseases progress, predict who is at risk, and deliver effective and innovative treatments. This requires collaboration among biomedical engineers, geneticists, biochemists, mathematicians, computer scientists, clinicians and researchers.

Hopkins has also established the Institute for NanoBio Technology, bringing together diverse experts to conduct research at the atomic or molecular level.

Just this month, the Institute announced it found a way to use a very brief burst of electricity to release biomolecules and nano particles from tiny gold launch pads. This technique may someday be used to disperse small amounts of medicine, on command, with increased precision, from a chip implanted in the body. Meanwhile, Hopkins Applied Physics Lab is leading a vast inter-disciplinary team in a project funded by DARPA to develop in just a few years a bionic arm that looks, feels and performs like a natural limb. That is the way future scientific inquiries will be conducted, and Chairman Barton's bill recognizes this reality. Biomedical research is an inter-disciplinary challenge.

Creating a Common Fund to promote trans-NIH research activities represents an important commitment to collaborative science. It is the quickest and most sensible way to find cures and treatments. The Common Fund will encourage new high-risk ideas that bring together investigators from fields that have not previously collaborated.

I hope a few areas in the bill can be clarified. First, awards from the Common Fund should include a mechanism to support young investigators. Most ideas that turn into Nobel Prizes come from investigators before they reach the age of 40. Second, it is important that the Common Fund empower small groups as well as large inter-disciplinary groups. Some big ideas still come from small groups.

I am convinced we are on the cusp of a dramatic transformation of health sciences discovery. Just think what would happen if we could come up with ways to prevent diabetes or chronic lung disease or Alzheimer's. Think of the dramatic impact this would have on shrinking the Medicare and Medicaid budgets, not to mention the dramatic impact of millions of suffering Americans.

The NIH is the engine that drives American biomedical research. The more we can do to increase the horsepower of that engine, the faster we can discover cures and treatments on a broader scale.

That concludes my remarks, Mr. Chairman.

CHAIRMAN BARTON. Thank you.

[The prepared statement of Dr. Edward Miller follows:]

PREPARED STATEMENT OF EDWARD D. MILLER, M.D., CHIEF EXECUTIVE OFFICER, JOHNS HOPKINS MEDICINE

### **Introduction**

Mr. Chairman and members of the Committee, thank you so much for inviting me to testify today at this very important hearing. I am Ed Miller, Dean of the Medical Faculty and CEO of Johns Hopkins Medicine. Johns Hopkins Medicine is the organization that represents The Johns Hopkins University School of Medicine and Johns Hopkins Health System.

Let me start by commending leaders in Washington for their foresight in doubling the National Institutes of Health (NIH) research budget between 1998 and 2003. Many of the startling advances in identifying early indicators and causes of diseases are the result of those well-spent federal research dollars. I am convinced we are on the cusp of a dramatic transformation in health science discovery and cures.

I would like to recognize the persistence of Chairman Barton in developing draft legislation that embraces the importance of biomedical research. We are grateful to you for reaching out to us and for caring about NIH enough to want to make it "better," and for leading the way to provide much needed increases in funding. The bill's provision for a 5 percent increase in annual funding is hugely important and it will accelerate crucial research. In addition, the creation of a "Common Fund" to promote trans-NIH research activities represents an important commitment to collaborative science. We at Johns Hopkins believe this is the quickest and most sensible way to find cures and treatments.

### **Justification of NIH Funding**

Congressional and administration support for biomedical research has helped to transform our ability to detect disease, treat patients, and deliver healthcare with greater effectiveness and affordability. At the same time, the return on investment for the American taxpayer has been high, as research has fostered discoveries that have led to new patents and products, and to the creation of new companies and job opportunities.

However, today the NIH budget is facing severe constriction. Indeed, one could say the federal funding of life sciences is in a crisis. For FY 2006, the NIH budget was cut in both nominal and real terms. For FY 2007, the budget is essentially frozen. This marks the third year in a row NIH funding has been cut, when adjusted for inflation. The biomedical research enterprise created by the NIH doubling has been cut by nearly 11 percent in real terms since 2003. Going forward, at a minimum for NIH, anything less than a funding level at least equal to the medical inflation index is a cut, and will weaken the nation's role as a worldwide leader in the biomedical field.

At Johns Hopkins, we have annually led the nation in NIH research dollars and we have made significant investments in young investigators to support the nation's efforts to advance science. However, there has been a marked decline in grants awarded to our School of Medicine. Fewer projects are being funded and NIH support of on-going investigations is being cut. Recent figures suggest that the number of grants and overall funding levels have declined. In FY 2002, the average funding level per grant was \$142,210 for the School of Medicine. By FY 2006, the funding level dropped nearly \$50,000 per grant to \$92,683, a decline of 34.8 percent. Hardest hit are America's young researchers. I fear we may lose a generation of enthusiastic, inquisitive scientists if they conclude NIH grants are out of reach. We must not let that happen.

The increased and sustained funding for biomedical research is important to the majority of Americans. According to public opinion polling conducted in 2005 by Research!America, 58 percent of Americans say that increasing U.S. funding for medical and health research now is essential to our future health and economic prosperity. Similarly, 79 percent of Americans agree that even if it brings no immediate benefits, basic science research which advances the frontiers of knowledge is necessary and should be supported by the federal government.

While the President and Congress have embraced the notion that funding for basic research is essential to strengthening America's competitive standing in the world, funding for biomedical research has not kept pace with this commitment. Aggressive, stable, and sustained federal spending on the NIH and biomedical research must be understood and embraced as a critical component of America's competitiveness. The fact is federal investments in biomedicine and basic science across the disciplines have taken the U.S. to the leading edge of innovation. The question we now face is whether as a country we are willing to pay the price to remain in the lead.

We believe the 5 percent increase in annual authorizations proposed is a sound investment. Sustainable and predictable funding levels for the NIH are critical to allowing researchers to deliver improved treatments that not only enhance quality of life for patients but can reduce health care costs.

### **How Research Can Impact Health Care Cost**

When advocates for increasing biomedical research funding meet with members of Congress and their staff, they are often asked: what have we to show for the money that NIH has received in the past? As we think about this question it is important to recognize the pace of biomedical research and science in general is often slow and unpredictable. It may be years before we can point to specific therapies or new medical devices that can trace their origins to recently funded efforts. But the simple answer is: we have a great deal to show! Here are four powerful examples of what Johns Hopkins scientists have accomplished in terms of improving healthcare and reducing costs thanks to NIH support.

#### *Detection of Vision Problems of Diabetics*

Diabetes is the leading cause of blindness in adults, with 12,000 to 24,000 new cases each year. Early identification of retina disease is critical to stave off vision loss, especially for the 10 million diabetics who are 60 years or older, most of them on Medicare or Medicaid. Yet more than half of all diabetics fail to get an annual eye exam

as recommended by the American Diabetes Association. To address this dilemma, Dr. Ran Zeimer, director of the Ophthalmic Physics Laboratory at Johns Hopkins Wilmer Eye Institute, came up with a novel solution after more than a decade of research: why not develop an easy-to-use digital camera that tests for retinopathy when diabetics visit their primary care physicians for check-ups?

Thanks to NIH support, Dr. Zeimer perfected an instrument called the DigiScope. The DigiScope takes images of the retina in just minutes as patients sit in front of an automated camera and look at a series of blinking lights. These images are then transmitted via the Internet to a reading center for expert interpretation. Over 20,000 individuals not under the care of an ophthalmologist have been screened to date in primary care physicians' offices. Those with vision-threatening disease have been identified and referred to eye specialists. In most cases, diabetics without complications are spared visits to an ophthalmologist, while Medicare and Medicaid are spared an expense.

#### *Advances in Treatment for Sickle Cell Patients.*

Thanks to continuous NIH grants extending back to 1982, Drs. George Dover and Samuel Charache of Johns Hopkins spent their careers fighting sickle cell disease – a miserable, inherited illness in which sickle-shaped red blood cells get stuck in narrow channels and block blood flow to tissue and vital organs. Patients with sickle cell disease – 72,000 in the United States – suffer frequent bouts of fatigue and shortness of breath, joint and body organ pains that turn excruciating and lead to frequent hospitalizations. The pneumonia-like conditions, chest pains, and fever can be life-threatening. Until fairly recently, early death was the norm, with life expectancy for a sickle cell patient projected to be only 20 to 30 years.

In the 1990s, Drs. Dover, Charache, and their Hopkins research team found that a cancer drug (hydroxyurea) did remarkable things for sickle cell sufferers. A 1995 NIH-supported multi-center study proved hydroxyurea therapy dramatically reduces the frequency and severity of painful episodes, hospitalizations and transfusions. In a 2003 study, daily hydroxyurea doses led to 30 percent fewer hospital days, 58 percent fewer transfusions and a 40 percent reduction in deaths. Today, hydroxyurea therapy is recommended for adults and adolescents with moderate-to-severe recurrent pain. As a result, the life expectancy for sickle cell patients has doubled.

There have been financial benefits, too. According to another NIH-sponsored study, hydroxyurea therapy saves the U.S. health care system \$5,210 per sickle cell patient per year. With 72,000 Americans suffering from sickle cell disease, the potential annual savings is more than \$375 million.

#### *Faster Diagnoses in Emergency Rooms*

With the existing threat of bioterrorism, it is crucial to find ways for swiftly identifying patients in hospital emergency rooms who have biochemical pathogens or life-threatening infectious diseases, such as meningitis, sepsis and bacterial endocarditis (an infection of the inner lining of the heart or heart valves). Current testing methods are time-consuming and usually lead to delays in diagnosing and treating these diseases. The current blood and culture tests for some diseases can take 24 hours or more.

Dr. Richard E. Rothman of Johns Hopkins Department of Emergency Medicine is working on novel ways to identify multiple blood-borne and pulmonary infectious diseases and bioterrorism pathogens in a hurry. His patented molecular diagnostic tests involve both exhaled breath and body fluids. Early experiments have shown these new diagnostic tools can detect 25 common bacterial infections and five categories of bioterrorism agents in fewer than 4 hours, and faster response times are expected as the diagnostic tools are fine-tuned.



### *Cell-Based Therapies for Heart Attacks*

Heart attacks represent a critical health problem facing this country. Each year, 565,000 Americans suffer heart attacks, 300,000 have recurring heart attacks, and 3 million deal with congestive heart failure. The costs for these patients are staggering: an estimated \$403 billion in 2005, with outpatient costs alone consuming \$120 billion.

Researchers are on the cusp of developing remarkable therapies that could revolutionize coronary treatment. One laboratory research group led by Hopkins' chief of cardiology, Dr. Eduardo Marban, is studying a treatment using a patient's own cardiac stem cells to repair damaged heart tissue soon after a heart attack and to regenerate weakened heart muscle. This could avert the need for expensive heart transplants. By using a patient's own cardiac stem cells, there also would be no risk of an immune-response rejection.

Meanwhile, Hopkins cardiologist Dr. Joshua Hare is engaged in a project that involves clinical trials with recent heart attack patients who are being given injections of adult bone-marrow stem cells. Dr. Hare's research revealed that stem cells harvested from a pig's bone marrow and injected into another pig's damaged heart restored heart function and repaired up to 75 percent of the damaged muscle in just two months. A \$12 million dollar, five-year NIH grant to the Johns Hopkins Heart Institute is making this exciting work possible.

### **Why Johns Hopkins Supports the Common Fund**

While the research efforts outlined above have produced improvements in clinical care and are driving a radical change in treatments, shifting to a new paradigm in how we fund and conduct biomedical research requires new thinking that crosses traditional boundaries. Medical centers have traditionally housed clinical researchers and basic scientist separately based on their departmental affiliations. These affiliations can create artificial barriers to collaborative research efforts. For some types of research, it often makes more sense for researchers from different departments to be co-located to facilitate interactions.

At Johns Hopkins, we have been able to tear down some of the traditional silos separating the branches of medical science to create a village of investigators to find cures and advance research. That work has been supported through various sources, but the most important source for biomedical research, the NIH, also needs a vehicle to sustain research that crosses these traditional silos.

The proposed Common Fund that will support trans-NIH research activities would represent an important commitment to collaborative science. At John Hopkins, we see this as the quickest and most sensible way to find cures and treatments. The movement to supporting a village of investigators is critical in combining all that we have learned to advance cures. However, it is important to note that this type of research is also not a silver bullet. We need to strike a balance between funding traditional research efforts and trans-NIH research.

The reason we need to create the Common Fund and support trans-NIH science can be easily seen in the area of cancer treatment. In 1971, when President Nixon signed the National Cancer Act, the word cancer was equated to a death sentence. According to the National Cancer Society's "Cancer Facts and Figures 2006," for all races the overall cancer survival rate was only 50 percent in 1974. Today, while survival rates fluctuate for particular cancers or populations, in almost every category we have improved survival rates. For example, in 1974 the survival rate for breast cancer for all women was 75 percent, while the most recent data available (1995-2001) report a survival rate of 88 percent. During these same time periods, the survival rate for colon cancer increased from 50 percent to 64 percent.

These survival rates increased because we were able to change how the disease was treated over the past 25-years, improving diagnostic techniques and expanding treatment

options. However, on September 16, 2006, researchers at Johns Hopkins announced that they had cracked the genetic code for breast and colon cancers. This information is the equivalent of looking at the enemy's game plan and revealed that the average number of mutant genes in each cancer is about 100, and at least 20 of them are likely to be critical for tumor formation. Just as important, the investigators found that each cancer has a different blueprint, so we now know that no two patient diseases are identical. This will not only guide cancer research for the next decade, it will lead to a better understanding why patients respond differently to the same therapies.

While this announcement is critical to advancing the treatment of cancer, we need to step back and understand what went into this discovery. The team used 22 cancer samples and information from the Human Genome Project to examine the more than 13,000 best-known genes. Then, the team examined the DNA code of the 13,000 genes by dividing each gene into overlapping sections, to obtain 130,000 sections for analysis. Then, the samples were amplified through more than 3 million biochemical reactions. Next, the sequences were fed through a computer to compare normal sequences with those from the tumor samples. More than 800,000 suspicious regions were visually inspected, one by one, to verify true mutations. In the end, the Hopkins team combed through 465 million nucleotides, which are the individual chemicals that pair together to build the rungs of the DNA ladder that compose genetic instructions.

It is important to understand that this work required a large, diverse team. The Johns Hopkins research team alone included 13 investigators and countless others at the University of South Carolina, Case Western Reserve University, University Hospitals of Cleveland, Texas Southwestern Medical Center, University of Maryland, Howard Hughes Medical Institute, and Agencourt Bioscience Corp. The success of this project is due to the village of researchers and recent advances in DNA sequencing and bioinformatics.

To support and advance this type of research, various institutes and centers, many of which are virtual, have been organized at Johns Hopkins. These centers of interdisciplinary research teams include not only investigators from different departments within the School of Medicine, but faculty from different schools and divisions across Johns Hopkins University as a whole. Below are a few more examples of these efforts.

#### *Institute for Computational Medicine*

Johns Hopkins University created the Institute for Computational Medicine (ICM) – the first of its kind in the world - because the nature of biomedical research has been transformed during the past decade. This transformation has been driven in large part by the development of new technologies for high throughput data generation which now make it possible to acquire gene sequences, measure the complement of genes and proteins expressed in cells and/or tissues, map protein-protein interactions and image functional properties of cells, tissue and organs under a wide range of conditions. The impact of these technologies on identification of the cause, diagnosis and treatment of human illness will be profound.

It will soon be common for clinical research studies to collect genetic, transcriptional, proteomic, imaging and clinical data from every patient in large, carefully selected cohorts sharing a specific disease diagnosis. The challenge of the coming decade will be how best to use these multi-scale biomedical data to gain a quantitative understanding of disease mechanisms.

#### *Institute for NanoBio Technology*

The Institute for NanoBio Technology (INBT), hopes to revolutionize health care by bringing together expertise from medicine, engineering, and public health to create new knowledge and groundbreaking technologies. Research is currently underway in the

following areas: cancer, cystic fibrosis, vaccines, asthma, hemophilia, spinal cord injury and peripheral nerve regeneration.

Approximately 100,000 children and adults worldwide are diagnosed with cystic fibrosis, a fatal genetic disease. While antibiotics treat infections caused by the disease and expectorants allow clearing the airways of mucus that makes it difficult to breathe, no cure is available. The DNA sequence that could cure cystic fibrosis was discovered years ago, but a successful therapy has not yet been developed. The challenge lies in designing a therapeutic DNA carrier that can reach cells affected by the disease. However, since cells in the airway are coated with a mucus barrier, delivery is very difficult. The Institute's goal is to create nanoparticle carriers with recognition and binding properties that can overcome the mucus barrier and attach therapeutic genes to lung cells.

Current therapies for cancer, including radiation and chemotherapy, are destructive to the body, often causing negative side effects and additional health problems. Techniques and methods for diagnosing and monitoring cancer often slow treatment time and reduce overall effectiveness. However, what if you could simultaneously detect malignant cells, image and treat them, and monitor efficacy of the treatment inside the body? Over the next 10 years, the Institute plans to develop nanoscale devices that detect cancer cells, report relevant diagnostic information, and deliver chemotherapeutic agents or therapeutic genes directly into the malignant cells. Targeting these devices to only interact with cancerous cells would spare healthy cells, greatly reducing or eliminating side effects that accompany many current cancer therapies. Also, simultaneous imaging and molecular profiling would allow non-invasive monitoring of tumors and treatment efficacy, resulting in better and faster patient care.

#### *Institute for Basic Biomedical Sciences*

The Institute for Basic Biomedical Sciences (IBBS) was created to focus on a number of biological problems including epigenetics, sensory biology, metabolism and obesity, cell dynamics, drug addiction, chemoprotection, transport biology and high throughput approaches to biological research. The institute brings together experts from fields including biology, physics, chemistry, mathematics, computer science and engineering.

Research efforts include bringing together a broad range of scientific expertise in both experimental and theoretical biology to further study the advances already made in genomic studies. IBBS researchers will examine how cells and whole organisms are structured, how they function and how they control interactions of the multitude of chemical compounds they contain.

Meanwhile, other researchers will study how cells use sugars and fats to build molecules required for survival, how cells regulate the conversion of food into energy, and how the body regulates levels of hormones and other chemicals in response to available nutrients. Research will focus on metabolism at a cellular level looking at factors influencing cell survival, growth and aging. At the level of the whole organism, the IBBS will address how nutrients, hormone levels and energy usage affects reproduction, exercise capacity, cognitive function, feeding behaviors and longevity, which is important in understanding obesity and diabetes.

#### *The Future of Surgery: I4M*

Today, surgery is based on technology and tools that have not truly changed in decades. Even with the development of minimally invasive surgery, skilled teams are asked to operate with limited knowledge, hampered sight, and outdated tools. However, computer-integrated systems and information-based technology can transform interventional medicine in the same way they have transformed manufacturing and other sectors of our society.

The Johns Hopkins University I4M (Integrating Imaging, Interventions, and Informatics in Medicine) initiative addresses the technological, clinical and educational challenges that need to be met in order to realize the full potential of this new age of healthcare. I4M enables physicians, engineers, and scientists from different departments and schools to work together, bringing the power of trans-disciplinary collaboration to solve problems that go beyond the scope of any single discipline.

#### *Next Generation of Artificial Limb*

A multi-disciplinary team of scientists and engineers are undertaking an ambitious project to develop a next-generation of mechanical arm that will look, feel, perform and be controlled like a natural limb. The advanced prosthetic arm will allow a user to button a shirt, tune a radio, and feel the warmth of a loved one's hand.

Today, the current state-of-the-art myoelectric arm allows users to control hand and arm movements by deliberately flexing a muscle or through mechanical movement. Still, these devices have relatively limited degrees of motion and can generally allow control of only one motion at a time. In order to improve on current technology, the team plans to develop a device able to perform at strengths, speeds and angles with 22 degrees of freedom to match the performance of the human arm while maintaining the person's ability to control the arm. To succeed in this effort will require breakthrough research in neural control, sensory input, advanced mechanics and actuators, and prosthesis design and integration.

While Johns Hopkins University Applied Physics Laboratory will lead the effort, the team includes faculty from Johns Hopkins' Schools of Medicine, Engineering, and Public Health. Furthermore, staff from research institutions and businesses around the world including: Arizona State University, the BioSTAR Group, California Institute of Technology, National Rehabilitation Hospital, Northwestern University and the Northwestern University Prosthetics Research Laboratory, Oak Ridge National Laboratories, Otto Bock Health Care (Austria), Rehabilitation Institute of Chicago, Umea University (Sweden), University of Michigan, University of Rochester, University of California, Irvine, University of Southern California, University of Utah and Vanderbilt University will participate in the project.

#### **Operations of the Common Fund**

As was noted earlier, while the Common Fund can help tear down barriers to advancing research and cures, its creation must not threaten the successes that the current model has produced. Instead, both traditional funding methods and the Common Fund must operate to support and enhance the best scientific research. As the committee moves forward with the creation of the Common Fund, I hope you will consider these important elements.

1. Awards from the Common Fund should include a mechanism to support young investigators. Most ideas that turn into Nobel Prizes come from investigators before they reach the age of 40. Support for their work must continue. While some young investigators will continue to seek support from traditional NIH funding streams, we also want to support these young investigators efforts on broad research projects.

On September 17, 2006, Carol Greider of the Johns Hopkins School of Medicine was awarded the most prestigious prize in American medicine - the Lasker Award. Dr. Greider, age 45, will share the award with two scientists who participated in the co-discovery. The award is based on findings of cell

function and genetics, which occurred twenty years ago, and is considered today to be one the most advanced areas of biomedical research.

2. It is important that the Common Fund empower small groups as well as large inter-disciplinary teams. Some big ideas and important research programs can come from smaller groups and these ideas need to be equally supported.
3. While some collaborations are more natural, the Common Fund needs to be used to encourage new, high risk ideas that bring together investigators from fields that have not previously collaborated. Encouraging these types of projects will promote new ideas and new groups of scientists and clinicians working together. These efforts can change science and medicine and currently cannot be funded through the regular channels.
4. Science and technology is changing much faster than ever before and funding mechanisms need to change as well. While the Common Fund is a step in the right direction, this effort along with traditional funding channels, need to be evaluated to ensure funding streams are as dynamic as the research. If the funding channels are not flexible, we could be limiting the research community's efforts to advance science.

Thank you for your efforts to strengthen America's biomedical research community. Johns Hopkins stands ready to support you in this important endeavor. I invite you and your staff to visit our campuses, explore our facilities and meet our researchers face to face. You will find no more persuasive argument for the inestimable value of investment in research than witnessing the innovative enterprise firsthand.

CHAIRMAN BARTON. Dr. Kirch.

DR. KIRCH. My name is Darrell Kirch, and I have the honor of serving as the President of the Association of American Medical Colleges. I am testifying today on behalf of the AAMC in support of the National Institutes of Health Reform Act of 2006.

The institutions we represent at the AAMC receive more than half of all the extramural funds awarded by NIH. Chairman Barton, we are indebted to you for your personal commitment to this legislation and to the NIH, and to the overall research effort for our Nation. As you mentioned earlier, you have indeed listened to us. We very much appreciate the significant changes that you have made over the course of the past year.

Over 18 months ago, the AAMC established an ad hoc committee of academic medical center leaders who reviewed and engaged the issues that arose as the legislation was developed. The members of our committee have reviewed the current draft, and they are pleased to see that the issues that we raised during those discussions have been addressed.

The AAMC believes that the NIH is indeed one of this Nation's greatest achievements. We concur with Dr. Zerhouni that the research

conducted and supported at NIH is transforming our day-to-day practice of medicine.

We also fully recognize the public's large investment in the NIH and in our member institutions where much of the research is carried out, and we recognize that this comes with a series of responsibilities and obligations. We believe that the biomedical investigators and research staff, both at the NIH and at our institutions, work extremely hard to maintain the trust that has been placed in them by our fellow citizens. But given the vital importance of this area of the public trust, we must do better. We believe the legislation you have proposed provides tools to enhance that accountability and the robust systems that are already in place at the NIH.

We join with all the medical research community and my colleagues here in applauding and supporting your call for additional funding above the inflationary levels of the Biomedical Research and Development Price Index. We need that support to foster new initiatives while sustaining current endeavors.

In particular, we strongly endorse the bill's recognition of the vital importance of those new investigators and investigator-initiated research to promote ongoing innovation and continued world leadership by our Nation's medical research enterprise.

The AAMC supports the establishment of a formal strategic planning process to identify areas of trans-NIH research to take full advantage of all the emerging scientific opportunities and the major public health challenges that we face. Mr. Chairman, we strongly agree with you that decisions regarding research projects to be supported should be based on scientific merit, not on political decisions.

The AAMC also endorses the creation of the comprehensive electronic reporting systems proposed in the legislation. We agree those will enhance the agency's accountability by providing transparency across the institutes and centers to all stakeholders. Scientists, patients, policy makers, we all will benefit from increased access to good information, and that will supply new insights into the value the public is deriving from its investment in this basic and clinical research.

The AAMC fully supports the creation of the dedicated source of funding, known as the Common Fund, to support trans-NIH initiatives. Our community is especially pleased that the legislation provides a reasonable rate of growth for the Common Fund that is linked clearly to the growth of the overall NIH budget.

We have provided the committee with several recommendations that we believe would strengthen the bill and build even greater community support. We respectfully ask the committee to consider those proposals, which I have attached to our testimony, either through technical

refinements in the legislative text or in the report language accompanying the bill when it takes up the legislation.

But most of all, we thank you all for your efforts on behalf of the NIH. We look forward to working with you and your colleagues in the House as well as the Senate and the NIH in support of the legislation as it moves forward.

Thank you very much for having me here today.

CHAIRMAN BARTON. Thank you, Dr. Kirch.

[The prepared statement of Dr. Darrell G. Kirch follows:]

PREPARED STATEMENT OF DARREL G. KIRCH, M.D., PRESIDENT, ASSOCIATION OF  
AMERICAN MEDICAL COLLEGES

We are indebted to the Chairman for his personal commitment to this legislation, to the NIH, and to the nation's medical research effort. Members of our *ad hoc* Working Committee on NIH Reauthorization have reviewed the current draft and are very pleased that many of the issues they have raised during the past year have been addressed. The AAMC endorses the legislation.

We strongly concur with NIH Director Zerhouni that research conducted and supported by the NIH has and will continue to transform the practice of medicine. The public's large investment in the NIH, and in our member institutions where much of the nation's medical research is carried out, comes with a series of responsibilities and obligations. The proposed legislation provides an appropriate vehicle to enhance the robust systems of accountability that currently exist at the NIH.

The AAMC supports the call for additional funding above the level of the Biomedical Research and Development Price Index (BRDPI) to foster new initiatives while sustaining ongoing endeavors. We strongly endorse the bill's recognition of the vital importance of new investigators and investigator-initiated research.

The AAMC supports the establishment of a formal strategic planning process to identify areas of trans-NIH research to take full advantage of emerging scientific opportunities and to address pressing public health challenges. We note that the proposed composition of the Council of Councils strikes an appropriate balance between the need for scientific input and the desire for broader representation of the various stakeholder communities, and concur that decisions regarding the research projects to be supported through the Common Fund should be based on scientific merit and not political decisions.

The AAMC endorses the creation of a comprehensive electronic reporting system across all of the NIH's institutes and centers, which will supply new insights into the value the public has derived from its sustained investment in basic and clinical research.

The AAMC fully supports the creation of a Common Fund to support trans-NIH initiatives and is pleased that the legislation provides a reasonable rate of growth for the Common Fund that is linked to the growth of the overall NIH budget. We propose that the Director of the NIH, in consultation with the Council of Councils, submit a thorough evaluation of the Common Fund and the research resources supported by the Fund prior to any decision about increasing the size of the Fund beyond 5 percent.

We have provided the committee with additional recommendations that we believe would strengthen the bill and build even greater community support. We respectfully ask the committee to consider these proposals, either through technical refinements in the legislative text or in the report language accompanying the bill.

My name is Darrell Kirch, M.D., and as President of the Association of American Medical Colleges (AAMC), I am pleased to have this opportunity to testify on behalf of the AAMC in support of the National Institutes of Health Reform Act of 2006. The AAMC represents all 125 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and 96 academic and scientific societies representing 109,000 faculty members. These institutions annually receive more than half of all extramural funds awarded by the National Institutes of Health (NIH).

Chairman Barton, we are indebted to you for your personal commitment to this legislation, to the NIH, and to the nation's medical research effort. I and several members of the AAMC's *ad hoc* Working Committee on NIH Reauthorization had the opportunity to meet with you in July to discuss your thoughts about the future directions for NIH, the need for increased transparency and accountability, and the role this legislation would play in achieving these objectives.

We recognize and appreciate the significant changes that you have made in this proposal during the course of the past year. In January 2005, the AAMC established an ad hoc committee of academic medical center leaders, co-chaired by Robert Kelch, M.D., Executive Vice President for Medical Affairs and CEO of the University of Michigan Health System, and Philip Pizzo, M.D., Dean of the Stanford University School of Medicine, to review and engage the issues that arose as this legislation developed. This committee reviewed earlier discussion drafts of this legislation that were released last year, and provided extensive comments that formed the basis for the statement the AAMC submitted to this committee last July. Our advisory committee has been fully apprised of the ongoing discussions between our respective staffs throughout the summer and has provided advice on the Association's positions throughout this process. Members of our committee have reviewed the current draft and are very pleased that many of the issues they have raised during the past year have been addressed.

The AAMC believes that the NIH is one of this nation's greatest achievements. The Federal Government's unwavering commitment to medical research, embodied in its investment in the NIH for nearly 70 years, has created a medical research enterprise that is the envy of the world and has contributed greatly to improving the health and well-being of all Americans, indeed of all humankind. We strongly concur with NIH Director Elias Zerhouni that the research conducted and supported by the NIH has and will continue to transform the practice of medicine.

We fully recognize that the public's large investment in the NIH, and in our member institutions where much of the nation's medical research is carried out, comes with a series of responsibilities and obligations. We recognize that we have been entrusted by the American people to be proper stewards of their funds, to conduct research in an unbiased manner, and to protect the safety and dignity of the thousands of individuals who volunteer to participate in research studies. We believe that the biomedical investigators and research staff both at the NIH and at our institutions work very hard to maintain the trust that has been placed in them by our fellow citizens. But given the vital importance of this area of the public trust, we must do better. We believe that the legislation you have proposed provides an appropriate vehicle to enhance the robust systems of accountability that currently exist at the NIH.

This legislation proposes changes that we believe will enhance the effectiveness of the NIH at a time when our nation faces unprecedented scientific opportunities and health challenges. We join with all members of the medical research community in applauding and supporting your call for additional funding above the level of the Biomedical Research and Development Price Index (BRDPI) to foster new initiatives while sustaining ongoing endeavors. In particular, we strongly endorse the bill's recognition of the vital importance of new investigators and investigator-initiated research to promote



ongoing innovation and ingenuity and continued world leadership by the nation's medical research enterprise.

The AAMC supports the establishment of a formal strategic planning process to identify areas of trans-NIH research to take full advantage of emerging scientific opportunities and to address pressing public health challenges. We are pleased that the planning process outlined in the legislation mirrors the actions that the NIH has already undertaken through its Office of Portfolio Analysis and Strategic Initiatives. We also note that the proposed composition of the Council of Councils strikes an appropriate balance between the need for scientific input and the desire for broader representation of the various stakeholder communities. Mr. Chairman, we strongly agree with you that the decisions regarding the research projects to be supported should be based on scientific merit and not political decisions.

The AAMC also endorses the creation of a comprehensive electronic reporting system, which we agree will enhance the agency's accountability by providing increased transparency across all of the NIH's institutes and centers to all stakeholders. Scientists, patients, and policymakers all will benefit from increased access to this information, which will supply new insights into the value the public has derived from its sustained investment in basic and clinical research.

The AAMC fully supports the creation of a dedicated source of funding, known as the Common Fund, to support the trans-NIH initiatives identified. Our community strongly believes that increases in this fund should not come at the expense of ongoing research programs, and we are pleased that the current legislation provides a reasonable rate of growth for the Common Fund that is linked to the growth of the overall NIH budget.

Once the Common Fund reaches 5 percent of the total NIH budget, the Director of the NIH, in consultation with the Council of Councils, is to submit recommendations to the Congress for further changes in the size of the Common Fund. We would propose modifying this provision by requiring the Director of the NIH, in consultation with the Council of Councils, to submit a thorough evaluation of the Common Fund and the research and research resources supported by the Fund prior to any decision about the size of the Fund. We believe that impartial assessment of the activities supported by the Fund, and its successes and shortcomings, is essential for the NIH, the Congress, and the stakeholders to make an informed judgment about the future size of and directions for the Common Fund.

Regarding the proposed uses of the Common Fund, we offer the following suggestions. Maintaining adequate funding opportunities for first-time NIH R01 applicants, and establishing "academic homes for clinical and translational science" by fully funding the number of Clinical Transformation Science Awards (CTSA) projected in FY2007 and 2008 are very high trans-NIH priorities. To meet these priorities will be especially challenging for the Institutes and Centers if the NIH budget remains constrained in the next two or more fiscal years. Accordingly, we propose that the report language make explicitly clear that monies from the Common Fund should be used to support first-time NIH R01 applicants, perhaps on a matching basis with the individual Institutes and Centers, and to fully fund the number of CTSA awards required to meet the NIH's previously projected target.

In the description of the activities to be identified by the Division of Program Coordination, Planning and Strategic Initiatives to be supported by the Common Fund, we propose the legislative language be amended to permit the support of research resources as well as research. We believe this recommendation is consistent with the support currently provided by the NIH Roadmap for analytical tools such as innovative technologies, databases, and research networks, and for training translational and clinical researchers.

We have provided the committee with these and some additional recommendations that we believe would strengthen the bill and build even greater community support. We respectfully ask the committee to consider these proposals, which I have attached to my testimony, either through technical refinements in the legislative text or in the report language accompanying the bill, when it takes up the legislation.

National Institutes of Health Reform Act of 2006  
 Technical Refinements  
 Submitted by the Association of American Medical Colleges  
 September 19, 2006

1. Maintaining adequate funding opportunities for first-time NIH R01 applicants, and establishing "academic homes for clinical and translational science" by fully funding the number of Clinical Transformation Science Awards (CTSA) projected in FY2007 and 2008 are very high trans-NIH priorities. To meet these priorities will be especially challenging for the Institutes and Centers if the NIH budget remains constrained in the next two or more fiscal years. Accordingly, we propose that the report language make explicitly clear that monies from the Common Fund should be used to support first-time NIH R01 applicants, perhaps on a matching basis with the individual Institutes and Centers, and to fully fund the number of CTSA awards required to meet the NIH's previously projected target.

2. In the description of the activities to be identified by the Division of Program Coordination, Planning and Strategic Initiatives to be supported by the Common Fund, we propose the following additions to the legislative language:

a. On page 21, line 3, amend "identify research that represents" to "identify research and research resources that address".

b. On page 21, line 8, after "additional research" insert "or to meet research needs".

We believe these changes would facilitate our first recommendation and are consistent with the support currently provided by the NIH Roadmap for analytical tools such as innovative technologies, databases, and research networks, and for training translational and clinical researchers.

3. We wish to be certain that our understanding is correct that all research to be supported by the Common Fund will undergo the same rigorous peer review of scientific merit required under 42 USC 289a.

4. Under the evaluation of the Common Fund, we propose that, in addition to the recommendations to Congress on the size of the Fund (page 32, lines 2-5), the Director of the NIH should submit an evaluation of the Common Fund and the research and research resources supported by the Fund. We believe that a thorough assessment of the activities supported by the Fund, and its successes and shortcomings, is essential for the NIH, the Congress, and the stakeholders to make an informed judgment about the future size of and directions for the Fund.

5. For the demonstration projects authorized under section (beginning on page 48), we propose that the Director of NIH submit an evaluation of these programs to the Congress at the end of the third year of the programs, including an assessment of whether the awards made under the programs met the goals and priorities established by the Director. We believe this information is essential for the NIH, the Congress, and the stakeholders to make an informed judgment about the continuation of the programs. We further propose that as part of this evaluation, consideration be made to supporting any

continuation of the programs through the Common Fund.

6. We note that the Secretary "may select" the Director of NIH to chair the Scientific Management Review Board (page 13, lines 23-24). We believe this would undermine the appearance of independence of this Board and would place the Director in a very uncomfortable situation if he or she exercises the authority granted to object to the Board's recommendations for major changes to existing Institutes and Centers (page 17, beginning at line 7). We propose eliminating the option for the Director of NIH the chair the Board. We support having the Director as a permanent member of the Board on an ex officio basis (page 12, lines 5-6). We also suggest that the presence of Institute and Center Directors on the Board could also raise questions about the Board's independence. The "interests" of the Institutes and centers might be better represented by appointing senior, accomplished, long-term awardees, who could provide a more independent perspective on the relevant scientific opportunities and needs, as well as on the functioning of the Institute or Center with which they have had a long history of interactions.

7. The bill states the Director of the NIH "shall approve the establishment of all national centers of excellence recommended by the national research institutes, other than centers recognized under section 414;" (page 23, lines 8-11). The purpose and justification for this new authority are unclear, nor is it clear why the national cancer research and demonstration centers authorized under 42 USC 285a-3 are uniquely exempted. Centers of excellence created by the individual Institutes have gone through rigorous review processes of scientific merit and programmatic relevance, and should not, in our view, require further approval by the NIH Director. We propose removing this provision.

**Darrell G. Kirch, M.D.** is president and chief executive officer of the Association of American Medical Colleges (AAMC), a position he assumed on July 1, 2006. Founded in 1876, the AAMC is a Washington, D.C.-based, non-profit association representing all 125 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and 96 academic and scientific societies. Through these institutions and organizations, the AAMC also represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians.

A distinguished medical scientist, educator, physician, and noted authority on organization and management issues at academic medical centers, Dr. Kirch's career spans all aspects of academic medicine and includes leadership positions at two medical schools and teaching hospitals, as well as at the National Institutes of Health (NIH).

Before becoming the AAMC's fourth president, Dr. Kirch was selected to be chair-elect of the association, and served as the co-chair of the Liaison Committee on Medical Education (LCME) and as a member-at-large of the National Board of Medical Examiners (NBME). He also has served as chair of the AAMC's Council of Deans Administrative Board and as chair of the American Medical Association's Section on Medical Schools.

Dr. Kirch comes to the AAMC after six years as senior vice president for health affairs, dean of the college of medicine, and CEO of the Milton S. Hershey Medical Center at The Pennsylvania State University, where he and his leadership team are credited with revitalizing the institution and guiding it through a period of major expansion. During his tenure, the college of medicine received its full accreditation from the LCME, and the medical center showed exceptionally solid fiscal results and dramatic growth in clinical activity. Under his stewardship, total research funding for the Penn State Hershey campus also grew from less than \$55 million to more than \$100 million in

only five years. Before joining Penn State, Dr. Kirch held a number of leadership positions at the Medical College of Georgia from 1994 to 2000, including dean of the medical school, senior vice president for clinical activities, and dean of the school of graduate studies.

As a psychiatrist and clinical neuroscientist, Dr. Kirch is a leading expert on the biological basis of and treatments for severe neuropsychiatric disorders. Following the completion of his residency training at the University of Colorado Health Sciences Center, he joined the National Institute of Mental Health (NIMH), in Bethesda, Maryland, where he was named acting scientific director in 1993.

Dr. Kirch is a native of Denver and received both his B.A and M.D. degrees from the University of Colorado. He has had an active career as a clinician and researcher, and has held medical faculty positions at Penn State, the Medical College of Georgia, and George Washington University.

Dr. Kirch is an active member of several professional societies, including the American College of Psychiatrists, the American Medical Association, and the American Psychiatric Association. A prolific writer and public speaker, he has published more than 100 articles and made over 130 presentations to national medical and scientific organizations.

CHAIRMAN BARTON. Dr. Eckel.

DR. ECKEL. Chairman Barton, Congressman Dingell, and members of the committee, as immediate past president of the American Heart Association and on behalf of the American Heart Association and our more than 22 million volunteers and supporters, I want to thank you for the opportunity to testify on the National Institutes of Health Reform Act of 2006. I salute you for your leadership in taking on an issue of such importance to the health of our Nation.

I also want to note that our Chief Executive Officer, Cass Wheeler, is here today to demonstrate the Association's support for your work.

Over the past 50 years, the improved diagnosis and treatment of heart disease and stroke has led to a--we have seen a remarkable increase in survival. According to the NIH, 1.6 million lives since the 1960s that otherwise would have been lost to heart disease alone.

Yet in spite of the progress, the sad and alarming truth is that we now may be losing ground. An estimated 71 million American adults still suffer from cardiovascular disease. Although we have increased our educational efforts, studies suggest that escalating rates of diabetes, obesity and other risk factors may actually reverse four decades of declining mortality.

To make matters worse, demographic trends will soon worsen the situation. As the Baby Boom generation ages, cardiovascular disease will spike dramatically and deaths from heart disease alone are projected to increase 2.5-fold faster than the population. We will soon face a cardiovascular crisis of staggering proportions with major implications for healthcare cost and the quality of care for our fellow citizens.

Mr. Chairman, there are no easy solutions. But we at the American Heart Association strongly believe that the proposals contained in this

legislation can provide the necessary framework and balance for real and positive change. It is an important and meaningful step in the right direction.

The Association supports this bill because the organizational adjustments, which improve the NIH's flexibility, collaboration and accountability, will help take an already world renowned research institution and its work to the next level.

These changes will direct resources more effectively and efficiently to current and emerging health problems, including those related to cardiovascular disease. One key example is the allocation of additional resources into trans-NIH research through the Common Fund.

I am currently a member of the Advisory Council of the National Institutes of Diabetes, Digestive and Kidney Diseases, where we have been engaged in a trans-NIH obesity initiative that involves 21 institutes and centers. These well-invested tax dollars will not only focus on the genetic and environmental basis of obesity and diabetes and establish an evidence-based approach for prevention, but also go towards reducing disability and death from cardiovascular disease. Moreover, from joint efforts with our private-sector colleagues, more effective therapies of prevention and management will certainly ensue. This, Mr. Chairman, is an example of the kind of collaboration that your legislation will facilitate through the Common Fund.

Mr. Chairman, I would be remiss if I didn't point out that although NIH's structural and operational reforms are certainly important, the agency also needs the necessary funds to carry out its mission. If we can match these reforms with a stable funding commitment recommended in the bill, the American Heart Association believes that we can be far more successful in the research needed to confront and overcome the terrible cardiovascular crisis that threatens to overwhelm the health and economic well-being of our Nation and the world.

Mr. Chairman, Congressman Dingell and members of the committee, I thank you for the opportunity to testify before you today.

CHAIRMAN BARTON. Thank you, DR. ECKEL. I want to thank the American Heart Association and NIH for making it possible for me to be here today. I am one of the 160 million Americans who has benefited from their research, so I personally appreciate what you have done.

[The prepared statement of Dr. Robert H. Eckel follows:]

PREPARED STATEMENT OF ROBERT H. ECKEL, M.D., PROFESSOR, DEPARTMENT OF  
PHYSIOLOGY AND BIOPHYSICS, UNIVERSITY OF COLORADO HEALTH SERVICES CENTER

Chairman Barton, Congressman Dingell and Members of the Committee, on behalf of the American Heart Association (AHA) and our more than 22 million volunteers and supporters, I want to thank you for this opportunity to present our views on the "National

Institutes of Health Reform Act of 2006” and for your leadership in taking on this issue of such great importance to our nation and fellow citizens.

I am saddened to report today that cardiovascular disease (CVD) remains the number one and most costly killer of Americans, and is fast becoming a worldwide epidemic – one of the so-called diseases of development. However, there is hope. Medical research can help reverse these lethal trends, and holds the key to an eventual cure for heart disease, stroke and all other forms of cardiovascular disease.

The American Heart Association has set the ambitious but feasible target of reducing cardiovascular disease and risk by 25 percent by the year 2010. And as major stakeholders in this debate, we have carefully reviewed the legislation before the Committee, and concluded that its proposed changes can help put us on the right path to meeting this goal.

#### **Research Makes a Difference**

Mr. Chairman, over the past 50 years, we have made enormous progress in the battle against cardiovascular disease. As many of us know from personal experience and loss, it was once all too common for a person who suffered a heart attack or stroke to die, or be severely debilitated or disabled following one.

In those early years of the CVD fight, the tools available to medical practitioners and researchers for diagnosis and treatment were limited, funding was scarce, and the problem was compounded by the fact that the vast majority of Americans knew little about what they could do in their day-to-day lives to help prevent this horrible and potentially lethal affliction.

However, through a strong partnership between the federal government and the medical research community and deliberate and focused action, we have made great strides since those first days. From the groundbreaking Framingham Heart Study and other studies that advanced our understanding of CVD risk factors, to new drugs, such as clot-busters and statins, we have witnessed first-hand what can be accomplished through medical research.

The improved diagnosis and treatment of heart disease and stroke has also been nothing less than remarkable – as has the improved survival rate. Indeed, according to the NIH, we have saved 1.6 million lives since the 1960s that otherwise would have been lost to heart disease. Much of this progress can be attributed to our investment in NIH-sponsored heart and stroke research.

#### **New Challenges Threaten Our Ability to Achieve Goals**

In spite of this progress in the war against cardiovascular disease, we are far from declaring victory. An estimated 71 million American adults now suffer from heart disease, stroke, and other forms of CVD. The morbidity and mortality rates are still staggering. Nearly 2,500 Americans die of CVD each day – an average of one death every 35 seconds. That is the equivalent of losing one entire small town in America every 24 hours. The alarming truth is that we may be losing ground. Although we have increased our educational efforts, studies suggest that increased rates of diabetes, obesity and other risk factors may reverse four decades of declining mortality.

In addition, demographics will soon worsen the situation. As the baby boom generation ages, the prevalence of cardiovascular disease will increase dramatically, because although this disease can strike at any stage of life – the likelihood increases with age. Deaths from heart disease alone are projected to increase 2.5 times faster than the population. Mortality from the most common type of stroke is projected to increase by nearly 100 percent between 2000 and 2032. Beyond the toll in human suffering and death, cardiovascular disease also comes with a steep price tag. It will cost Americans an estimated \$403 billion in medical expenses and lost productivity in 2006 – more than any other disease and more than the projected budget deficit for this year. We will soon face

a cardiovascular crisis of staggering proportions, with major implications for health care costs and quality of care for our fellow citizens.

#### **Reforms in this Bill Address These Challenges**

We strongly believe that the reforms proposed in this legislation are both prudent and necessary to help address these challenges. In 2002, the AHA testified before the Institute of Medicine (IOM) on NIH's "optimal organization structure." We recommended four key principles – transparency, flexibility, collaboration, and translation – to guide this ideal architecture. Many were reflected in IOM's recommendations issued in 2003 and are in turn, embodied in the legislation before the Committee today.

For example, the creation of a new Division for Program Coordination, Planning, and Strategic Initiatives will give the Director the *flexibility* needed to respond to emerging disease threats in an agile, comprehensive and coordinated manner that does not exist today. The creation of a common research fund to support more trans-NIH research recognizes the need for *collaboration* on problems like obesity, which is a significant risk factor for heart disease, stroke, diabetes, cancer, and other diseases, and also supports clinical research, which helps enable the *translation* of basic research into patient care. In addition, the new agency-wide performance system and consolidated reporting would help promote greater *transparency*, produce more accurate and credible data on disease funding and outcomes, and enable patient advocacy groups to use this data to make a strong and credible case for federal funding for medical research.

The bill authorizes 5 percent increases for NIH for each of the next three fiscal years (FY 2007-2009.) We would ideally have hoped for a higher level. Since the end of the so-called "doubling period," funding for NIH has declined in real terms (adjusted for medical research inflation) in every year; it would take an increase of more than 10 percent in FY 2007 just to restore NIH to its post-doubling level. However, we recognize the current budget realities: the level set for

FY 2007 reflects budget recommendations made by the American Heart Association and the broader medical research community. If we can match these reforms with the stable funding commitment recommended in the bill, the American Heart Association believes that we can be much more successful in the research needed to confront and overcome the terrible cardiovascular crisis that threatens to overwhelm the health and economic well-being of our nation – and the world.

I would now like to turn to the Association's specific observations and recommendations about key proposals in the legislation.

#### **The Common Fund**

In addition to promoting "shared funds" controlled by the Institutes' and Centers' directors, the legislation would establish a "common fund" to focus entirely on trans-NIH research projects – those that may cut across more than one disease, or where one disease or risk factor may influence another. This provision implements IOM's recommendation to "enhance and increase trans-NIH strategic planning and funding," and we agree that interdisciplinary interaction is critical to promoting new initiatives and aligning medical research.

Two recent examples of trans-NIH research funding illustrate the tangible benefits of collaborating on cardiovascular disease: (1) the NIH strategic plan for obesity research; and (2) the NIH blueprint for neuroscience research.

Obesity is a major risk factor for heart disease and stroke, as well as for many other diseases, including diabetes, certain cancers, liver disease, osteoarthritis, sleep apnea, and depression. And obesity does more than affect life lines; it also affects government's bottom line – costs. According to a recent study by economists Kenneth Thorpe and David Howard, obesity and other chronic conditions were major factors driving virtually

all Medicare spending growth for the past 15 years. The rate of obesity among Medicare patients doubled from 1987 to 2002, and spending on those individuals rose more than twofold.

The increase in obesity over the past 30 years has been fueled by a complex interplay of many factors and calls for a broad spectrum of research, including molecular, genetic, behavioral, environmental, epidemiological, and clinical studies. The NIH strategic plan for obesity research provides a guide for coordinating obesity-related research activities across the organization based on the identification of areas of greatest scientific opportunity and challenge. It is a wise choice as these well-invested taxpayer dollars will not only focus on the genetic and environmental basis of obesity and diabetes and establish an evidence-based approach for prevention, but also go towards reducing disability and death from cardiovascular disease. Moreover, through joint efforts with our private sector colleagues, more effective therapies of prevention and management will certainly ensue.

The NIH blueprint for neuroscience research is supported by 15 Institutes and Centers. Blueprint initiatives have focused on neuroscience tools, training in the neurobiology of disease for basic science, genome analysis, neuroimaging, genetic mouse models, core research facilities, and clinical assessment tools. By pooling resources and expertise, this collaborative effort helps advance neurosciences and the emergence of new technologies that will lead to breakthroughs in stroke and other brain disorders.

These are just two examples of the many collaborative efforts within the NIH that increase the effectiveness of the nation's investment in health-related research

#### **Authorizations for the Common Fund**

We are pleased that the draft legislation sets a ceiling on trans-NIH research at five percent – the same level as recommended in the IOM report. If the NIH receives increases assumed in the draft legislation of five percent-a-year through FY 2009, the Common Fund could reach the targeted five percent level as early as FY 2008.

#### **Agency-wide Reporting System**

The AHA supports the creation of an agency-wide electronic reporting system to catalogue NIH's research activities in a standardized format. The current decentralized data collection mechanisms make it difficult to determine how much has been spent on cardiovascular research and for what purposes. This year, for example, cardiovascular-related research was conducted by 18 Institutes and Centers, with their own distinct methods of reporting.

Other provisions in the bill would require the Director to submit biennially a report to Congress that lays out the strategic plans and research activities of the entire agency in a comprehensive fashion. As previously noted, these new reporting requirements should help increase the transparency of NIH research activities and give us the information we need to make a compelling case for adequate research funding.

Nevertheless, we are concerned that Section 403(a)(5) of the bill neglects to require a separate category for heart disease and stroke – the number one and number three killers of Americans, respectively, in the biennial report of the Director. We urge the Director to include a separate subsection for cardiovascular disease, or to include information for heart disease and stroke under the appropriate category in the same standardized format as all other diseases, disorders, and other adverse health conditions.

#### **Strategic Planning Process**

The Association supports the proposed strategic planning process that transcends – but does not supplant – the planning, priority setting, and research activities of individual Institutes and Centers. Many of these changes are being implemented now through the Office of Portfolio Analysis and Strategic Initiatives (OPASI). The proposed new



Division of Program Coordination, Planning, and Strategic Initiatives would carry on these activities.

One objective of this new coordinating function is to identify and plan for emerging scientific opportunities and rising health challenges that involve collaboration between two or more Institutes or Centers. Given its “Number One” killer status, we strongly recommend that cardiovascular disease be included as one of the challenges to be addressed in the strategic planning process. As part of this planning process, we urge the Division to develop long-term projections of the incidence and prevalence of chronic diseases in coordination with other appropriate Federal agencies. These long-term projections would help guide research efforts aimed at reducing the economic and health burden of an aging population.

#### **Scientific Management Review Board**

The bill would create an advisory council or “Scientific Management Review Board” to periodically review the NIH’s structural organization. The Association supports the requirement that the Board include the Directors of at least nine Institutes and Centers. We also support the requirement that the Board consult with organizations representing patients and that at least one Board meeting should address the needs and opportunities of patients and their families. We believe that the American Heart Association should be among the groups with which the Board consults on the NIH’s organization, as we are able to represent both patient and family views.

#### **Conclusion**

The AHA is heartened that Chairman Barton and the Committee recognize and appreciate the important role of patient stakeholders in NIH’s mission. We have made considerable progress over the years, but face daunting challenges in the years ahead. We support this legislation because we believe that the organizational and other changes recommended in this bill will help direct resources more effectively to current health concerns, and help bring about the achievements in research necessary to confront the cardiovascular crisis that threatens the health and economic well-being of our nation and the world.

CHAIRMAN BARTON. Dr. Furcht.

DR. FURCHT. Thank you, Mr. Chairman, Ranking Member and members, it is my privilege to be here today representing the Federation of American Societies For Experimental Biology, or FASEB. This is a coalition of 21 different scientific societies representing more than 80,000 biomedical researchers. On behalf of FASEB and the research community, I would like to thank you for your leadership and your continuing commitment to NIH.

In reauthorizing this critical agency, you have outlined a vision for increased transparency, common sense accountability and innovative progress in our battle against the scourge of diseases, and for meeting our most pressing public health needs.

The scientific community is especially grateful for your determination to authorize increases for NIH for each of the 3 years covered by your draft legislation. Your championing of NIH funding at a sustainable level above the cost of inflation is enormously important for both science and human health.

On behalf of FASEB, and as a physician scientist myself, I want to applaud your outstanding leadership on calling on NIH to emphasize and preserve investigator-initiated competitive peer-reviewed grants.

Investigator-initiated competitive research has proven extraordinarily successful in generating the research discoveries that have led to some of our most effective and important medical treatments. To illustrate this point, I would like to provide just a few examples of what investigator-initiated research really means. This is scientists across the country using evidence at hand and their own creative abilities to generate new ideas to solve serious problems. Investigator-initiated research has identified the BRCA 1 and 2 genes, which put women at very high risk for breast cancer, and has given us Tamoxifen, Letrozole and Herceptin, and other drugs to treat breast cancer. It has led us to clot busting drugs to halt heart attacks and statins, and high blood pressure medications to protect us from heart disease. In addition, premature infants are able to draw breath thanks to surfactant, discovered by researchers trying to understand how the lungs work.

FASEB believes wholeheartedly that by placing most of its resources in investigator-initiated peer-reviewed research, NIH ensures that Federal taxpayers' dollars are supporting the very best science. However, we also recognize that challenges arise that require larger scale resources or multi-disciplinary approaches. This is why FASEB supports the establishment of a Common Fund for research focused on critical public health challenges and evolving areas of scientific opportunities, as well as its growth to a final level of 5 percent. Clearly, discoveries in one field may have broad application to a host of diseases which is consistent with the idea of supporting cross-cutting multi-institute research.

In discussing the Common Fund concept, my colleagues within FASEB were able to name a number of ongoing projects that we believe fit this vision and spirit of the Common Fund as articulated by the NIH Reform Act. The Neuroscience Blueprint Obesity Initiative, Clinical and Translation Science Awards, Pathways to Independence Grants for first time investigators, the creation of trans-NIH genomics resources, and studies related to the interaction of genes on the environment are currently being funded or under consideration by the institutes and centers. We hope that the institutes and centers will be able to seek resources from the Common Fund to dedicate to these and other collaborative efforts.

We also strongly recommend that the vastly increased Common Fund resources be used to fund trans-NIH priorities such as funding first-time investigators, loan repayment programs that encourage physician scientists to stay in research.

Continuing to attract new investigators is key to maintaining the vitality of the biomedical workforce. With growing constraints on the NIH budget, we believe that there is no better use for the Common Fund resources than the creation of a sufficient pool of resources for new investigators.

Mr. Chairman, Ranking Member and members, FASEB and the scientists we represent are grateful for your sustained leadership to assure that NIH continues to excel in supporting the highest quality of medical science. In endorsing NIH reauthorization, FASEB is proud to join with you in paving the way for reinvigorated investment in medical research. We stand ready to work with you and your staff to move this important piece of legislation forward. Thank you.

[The prepared statement of Dr. Leo T. Furcht follows:]

PREPARED STATEMENT OF LEO T. FURCHT, M.D., BOARD OF DIRECTORS, FEDERATION OF  
AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

I am here today representing the Federation of American Societies for Experimental Biology or FASEB, a coalition of 21 scientific societies representing more than 80,000 biomedical researchers. It is an honor to appear before this Committee to support the reauthorization of the National Institutes of Health – the world's leading biomedical research organization.

A half-century of sustained public investment in NIH has dramatically advanced the health and improved the lives of the American people and of people around the globe. Mr. Chairman, it is my privilege today, on behalf of FASEB and the biomedical research community, to thank you and the members of Committee for your leadership and your continuing commitment to NIH. In reauthorizing this critical agency, you have outlined a vision for increased transparency, commonsense accountability and innovative progress in our battle against the scourge of diseases and for meeting our most pressing public health needs.

Through actively seeking input from the research community, you have developed a model for NIH that both improves upon the current system and preserves those aspects that have allowed NIH to achieve its global preeminence in medical research. The research community spoke, you listened, and we want to express our appreciation for your efforts and consideration.

The scientific community is especially grateful for your determination to authorize increases in NIH funding for each of the three years covered by your draft legislation. The enormous promise of medical and scientific research – in both lifesaving and economic terms – will not be realized without such support. Your championing of NIH funding at a sustainable level, above the cost of inflation, is enormously important.

On behalf of FASEB, and as a physician scientist myself, I want to applaud your outstanding leadership in calling on the NIH to emphasize and preserve investigator-initiated, competitive, peer reviewed grants. This mechanism allows highly skilled scientists to propose the direction and priorities for further research, based on their own expertise and insight. Investigator-initiated, competitive research has proven extraordinarily successful in generating the research discoveries that have led to some of our most effective medical treatments.

To illustrate this point I would like to provide a few examples of what investigator-initiated research really means: scientists all across the country using the evidence at hand and their own creative abilities to generate new ideas to solve serious health

problems. Investigator-initiated research has identified the BRCA 1 and 2 genes, which put women at very high risk for breast cancer, and has given us tamoxifen, letrozole and Herceptin to treat breast cancer. It has led us to clot busting drugs to halt heart attacks and statins and high blood pressure medications to protect us from heart disease. Premature infants are able to draw breath thanks to surfactant, discovered by a researcher trying to understand how lungs work. Insulin for diabetes, acyclovir for viruses, the HIV “triple cocktail,” Gleevec for leukemia – all of these breakthroughs, and many more, resulted from individual scientists pursuing questions of interest and importance and putting the pieces together to save and extend the lives of millions of people each year. Our nation trains and attracts the best scientific talent in the world; allowing these researchers’ intrepid imaginations to set the course of discovery is the best way to improve health and well-being.

FASEB believes wholeheartedly that by placing most of its resources in investigator-initiated peer reviewed research, NIH ensures that federal taxpayers’ dollars support the best science. However, we also recognize that challenges arise that require larger scale resources or a multi-disciplinary approach. This is why FASEB supports the establishment of a “common fund” for research focused on critical public health challenges and evolving areas of scientific opportunities as well as its growth to a final level of five percent. Clearly, discoveries in one field may have broad application to a host of diseases, which is consistent with the idea of supporting cross-cutting, multiple-institute research.

In discussing the “common fund” concept, my colleagues within FASEB were able to name a number of ongoing projects that we believe fit the vision and spirit of the “common fund,” as articulated by the NIH Reform Act. The Neuroscience Blueprint, Obesity Initiative, Clinical and Translational Science Awards, Pathways to Independence grants for first-time investigators, the creation of trans-NIH genomics resources, and studies related to the interaction of genes and environment are all currently being funded or under consideration by the institutes and centers. We hope that institutes and centers will be able to seek resources from the “common fund” to dedicate to these and other collaborative efforts.

We also strongly recommend that the vastly increased common fund resources be used to fund trans-NIH priorities such as funding for first-time investigators and loan repayment programs that encourage physician-scientists to stay in research. Continuing to attract new investigators is key to maintaining the vitality of the biomedical workforce, and with growing constraints on the NIH budget we believe that there is no better use for the common fund resources than the creation of a sufficient pool of resources for new investigators. This is particularly crucial now, as we try to keep our most talented young investigators in the pipeline by ensuring independent research support is available to them.

FASEB also strongly endorses your proposal to create an infrastructure to evaluate the NIH research portfolio to ensure that urgent public health needs and scientific opportunities are addressed in a timely manner. The reporting system which you have outlined will provide increased transparency and accountability.

This more transparent administrative structure would make NIH more accessible to the external community. Patient groups and researchers would have better access to information and have more direct input on program design. Because NIH funding is supported by federal tax dollars, it is essential that the agency inform both the public and elected representatives of the value of the research it supports. It is also critically important that NIH inform the public and members of Congress that the path to preventing and curing human disease requires a sustained and long-term investment in basic and clinical research.

It is clear that we all share a mutual desire to improve our nation’s health and well-being through the lifesaving research funded by NIH. NIH-supported research represents

a dual investment in the future of our nation: first, by helping to assure the health, security and quality of life of our citizens; and second, by training the current – and future – scientific and technical workforce needed to maintain our progress and keep the United States the world leader in biomedical research. In endorsing NIH reauthorization, FASEB is proud to join with you in paving the way for reinvigorated investment in medical research.

Mr. Chairman, FASEB and the scientists we represent are grateful for your sustained leadership to assure that NIH continues to excel in supporting the highest quality medical science. Although we have only had a short time to review the bill itself, and would welcome the opportunity to comment further in writing on some of the finer details of the language, we stand ready to work with you and your staff to move this important piece of legislation forward.

CHAIRMAN BARTON. Thank you, Doctor.

The Chair recognizes himself for the first series of questions. I have waited a long time for the answer to this question, so I want to make sure we get it on the record.

Do each of you and your organizations endorse the bill that is before us? We will start with you, Dr. Miller.

DR. MILLER. Yes, we fully support the bill before us.

CHAIRMAN BARTON. Dr. Kirch.

DR. KIRCH. As does the Association of American Medical Colleges.

CHAIRMAN BARTON. That is a yes?

DR. ECKEL. Yes. As does the American Heart Association.

CHAIRMAN BARTON. I am tempted to ask the same question again, but I won't. I can't tell you how hard we worked to get those yeses.

Do you seek passage in this Congress? Dr. Miller.

DR. MILLER. Yes, sir. I think this is important to America's health. Yes, it is that important.

CHAIRMAN BARTON. Dr. Kirch.

DR. KIRCH. The things this bill proposes are overdue, we support that.

CHAIRMAN BARTON. Dr. Eckel.

DR. ECKEL. I agree.

CHAIRMAN BARTON. Okay, and Dr. Furcht.

DR. FURCHT. We would hope that very much would occur.

CHAIRMAN BARTON. I think all of you in your opening statements commented on the Common Fund and how important that is to have a robust Common Fund. Would any of you like to elaborate on that? Anybody?

DR. MILLER. Let me start. I am used to the Common Fund as a dean of a medical school, it is called the Dean's Tax. Essentially, those are funds that come to the dean, and the dean is able to use those funds to drive new initiatives. I will give you one example. 18 months ago, Burt Vogelstein, one of our pre-eminent scientists, came to my office and said "Ed, I think I can sequence the whole genome for both breast cancer and

colon cancer, but it is going to cost about \$4.5 million; I have \$2.5 million, can you come up with another \$2 million?" Last week, in Science Express, Burt Vogelstein and his team published genome for those two cancers. That was an example where, without that funding available, that discovery could not have been made. That is a real breakthrough, and everybody will say that is a breakthrough because that is just the beginning of how we are going to find out how many missteps there are in the cancer and what happens and why a cancer occurs.

CHAIRMAN BARTON. Would anybody else want to comment on the Common Fund?

DR. KIRCH. I would just add that the notion of the Common Fund really parallels the way the world of science has changed. The four of us sitting at this table started our careers in a world where almost all science was individual investigator oriented. While as Dr. Furcht pointed out, that remains important. In the complex world we live in today, more and more projects are so complicated that they require broad teams of people drawn from different disciplines. The Common Fund simply recognizes that problems less and less are owned by a single institute, they cross institutes.

CHAIRMAN BARTON. Dr. Eckel.

DR. ECKEL. Mr. Chairman, the Obesity Strategic Plan at the NIH is a perfect example of this kind of collaboration. Directors Betsy Nabel and Allen Spiegel recently combined efforts to try to get NHLBI and NIDDK to take a leadership role here. As part of the advisory council I was involved, to some extent, in that process, and now 21 institutes and centers have signed on to this important area that is epidemic in our society.

Another brief case in point is the fact that I am an endocrinologist, but have recently stepped down as President of the American Heart Association. I am not a cardiologist, yet metabolic diseases, including obesity and diabetes, are so paramount in causing cardiovascular disease that I think the area of science I represent is important to cardiologists. Case in point.

CHAIRMAN BARTON. Dr. Furcht.

DR. FURCHT. Thank you. The Common Fund is extremely important to our scientists because many of the fundamental discoveries that are made in research aren't necessarily disease-specific. It is the creativity and the insight of an investigator finding an unintended observation, an unexpected observation that can sometimes lead to a tremendous breakthrough in finding cures for diseases that are not necessarily institute-specific or necessarily disease-specific at the outset. So we strongly encourage the benefit and the utility of the Common Fund.

CHAIRMAN BARTON. Well, my time is about to expire. I want to thank each of you and your associations for working with us. There has been a lot of give and take. I know that you all have been pressured by some in your organizations, and I appreciate the “give” that you have given, but you can tell them that you have been very good negotiators in getting people like myself, Mr. Dingell, and his staff to give back. We have truly worked back and forth and through numerous iterations so that we have a work product that I think we can all be proud of.

I appreciate your endorsement of the bill. I want to pledge to you that if we have a good markup tomorrow, and I am confident that this will be something that gets through the House very quickly. I am working very hard and I encourage you to help so that we can get it through the other body quickly also and get it done in this Congress.

With that, I am going to recognize the distinguished member from California, Mr. Waxman, for his questions.

MR. WAXMAN. Thank you, Mr. Chairman.

Dr. Kirch, let me start with you. I am sure you are familiar with the IOM report, Enhancing the Vitality of the National Institutes of Health, but I want to direct you to the specific section detailing IOM’s recommendation on how structural changes to the number of institutes and centers should be made.

It appears Chairman Barton’s mark is missing two critical elements contained in the IOM report; one, the director can reorganize the institute and centers without using the completely open public process. There is a requirement that he go through a public rule-making process, but that does not mean that a public hearing or forum of the type IOM recommends is required.

Secondly, under the bill, the director can reorganize institutes and centers on his or her own with the approval of the Secretary and after providing Congress with 90-days notice of the reorganization. This is quite different, as I read it, from the IOM report which says that the NIH director, along with an investigative committee, should make recommendations to Congress for reorganization after an open public process. Congress would then use the findings in the report to inform our actions in passing legislation to make structural changes at the NIH.

Do you agree with the IOM, that public hearings, both the scientific forums and the public forums, should be a requirement before any structural changes are made at the NIH? And do you agree that the bill should explicitly state that public forums are required?

DR. KIRCH. First, I would stress that the organization I represent, the AAMC, and the IOM are different organizations and independent organizations. I am familiar with the IOM report. I am also fairly

familiar with the structural workings of the NIH, having worked personally at the NIH for almost 13 years.

I am not an expert in how Congress and Federal agencies deal with issues like this. I can tell you that I believe that the complexities of the NIH structure, together with the complexities of science, are such now that our focus should be less on the ways NIH is divided and more on the tools that NIH is given to bridge institutes and centers. So our focus in this legislation has been on its provision of tools to bridge across institutes and centers.

MR. WAXMAN. So it isn't that you disagree with the IOM recommendation, it is that you are not an expert in it, and you want NIH to have as much authority as possible to reorganize the institutes and other agencies within NIH?

DR. KIRCH. What I am saying is that I believe the focus in this legislation has been on giving the NIH tools to bridge and transcend institutes. It does not appear to me that the focus of our discussions has been on the internal structuring of individual institutes.

MR. WAXMAN. Do you think that the director should be able to abolish institutes?

DR. KIRCH. My reading of the legislation is not that it gives the director unilateral authority to abolish institutes.

MR. WAXMAN. Well, let me put it this way: Do you agree with the Institute of Medicine that it should be Congress, not the director, actually making the structural changes at NIH?

DR. KIRCH. As somebody who works with all the Nation's medical schools and teaching hospitals, I would hope that Congress and the Federal agencies would find ways to work together to serve the public interest.

MR. WAXMAN. The Scientific Management and Review Board, as I understand it, has 21 members, including nine possibly from the largest institutes. Further, it can actually be chaired by the director of NIH. Since the director receives the recommendations and actually is provided a procedure to follow if he disagrees with them, it does seem unusual to also allow him to serve as the executive director.

Dr. Kirch, you indicated some concern here. Would you elaborate? And I would be interested in anybody else on the panel who might have concerns or suggestions about the membership.

DR. KIRCH. As I mention in my testimony, we have provided some additional comments that we hope the committee in its wisdom could deal with in the process. One of those comments is directed at the notion of the potential difficult position this could place an NIH director in, and we would hope there could be some discussion of that.



MR. WAXMAN. Anybody else want to comment on that issue on the panel?

DR. ECKEL. The American Heart Association, Representative Waxman, feels strongly that patient groups should have representation on that council. The American Heart Association is an example of an organization that stands for a significant disease burden in our society. So we would further recommend that an organization like the AHA be included on this council.

CHAIRMAN BARTON. The gentleman's time has expired.

Before we yield to Dr. Norwood, I would like to point out that the thesis of the gentleman's question is current law. The Secretary of HHS has the authority, under current law, to do some of the things that you have enumerated. The draft before us actually puts more public input, obviously not as much as you wish, but more into the process. So it is moving in the direction of the intent of your questions, as I understand them.

MR. WAXMAN. Mr. Chairman, if you would yield to me. The current law that allows the director to make some of these decisions has never been used. Here we would be adopting a very clear and specific authorization for them to do these things where they have never done it before. I think that invites it to be used, and I have questions about it. Perhaps we can discuss them.

CHAIRMAN BARTON. I understand, but we are not changing the authority you reference. My only point is that this is current law. That is not an addition that is in this draft.

We certainly have tried to empower the agencies. We have tried to empower public input to make it more open and more transparent. So we are moving in the direction that I think the intent of your question has implied.

MR. WAXMAN. Well, I disagree with you. Because the current law that has been there for some time, that has never been implemented, is something that NIH may not feel is the right path for them to take. But now we are saying, take this path. Some of these other procedures are added in, but I would rather not have that at all. I think Congress ought to be the one to make these final decisions.

CHAIRMAN BARTON. Mr. Norwood.

MR. NORWOOD. Thank you very much, Mr. Chairman.

Gentlemen, I have 5 minutes. I want to ask one question, and I would ask each of you to perhaps answer that in 1 minute so we can get through everybody.

Happily, everybody at the table seems to be in agreement that this is good legislation, it is long past due, and everybody seems to be okay with it, generally. I want to ask if any of you have anything about this

you think is wrong or should be changed at this point in time that is in our draft legislation.

Dr. Miller, could we start with you?

DR. MILLER. Well, I have looked at it very closely, and I believe the legislation addresses the issues we have concern with: that it supports young investigators through the Common Fund, it allows the Director to have additional funds to do transinstitute work, which I think is incredibly important; but the most important thing is that it increases the overall NIH budget, which I think is the most crucial element.

MR. NORWOOD. Thank you.

Dr. Kirch.

DR. KIRCH. As I said, we offered a number of suggestions. I would not put them under the heading of changing the legislation; rather, I view them as suggestions as to how it might be improved. They are too detailed to go into here, but in general they are adding some specificity in some areas to simply ensure that the intentions of the bill are carried out in the complex practice of science.

MR. NORWOOD. Have you offered these suggestions before?

DR. KIRCH. These have been provided to the committee.

MR. NORWOOD. And have they been provided in writing?

DR. KIRCH. Yes.

MR. NORWOOD. Okay. Pardon the interruption.

Just highlight a little bit more and then we can look at the details.

DR. KIRCH. Well, I share with my colleagues at the table a concern about our investigators of the future. They are an endangered group right now, and I think ensuring that the Common Fund could be applied to their development is a high priority that we would like to see specified.

DR. ECKEL. The American Heart Association has another concern beyond the council that ultimately reviews the decisions made for the Common Fund. In section 403(a)(5) of the bill, there is no language to require a separate category for heart disease and stroke, the number one and number three killers of Americans. The American Heart Association would urge the Director to include a separate subsection for cardiovascular disease.

So the agency-wide reporting system, at present, neglects heart disease and stroke. We would simply like that included.

MR. NORWOOD. Certainly appreciate that comment. Coming from you, I would say the same thing.

Yes, sir.

DR. FURCHT. FASEB is very supportive of this draft bill. I think, as was stated earlier, the most critical thing for us is the increase in the authorization for the NIH budget.

Whether we recognize it or not, there is a crisis in academia today where young people are turning away from our field of biomedical research because of the tremendous competition and the fear of failure, if you will, of having to compete in the academic marketplace. We think that by virtue of increasing this, creating the Common Fund that is split between the new increases in appropriated dollars coupled with the enhanced transparency and accountability, all have benefits that we would all like to see to improve the use of taxpayer dollars for biomedical research.

So we are very comfortable with that.

MR. NORWOOD. Part of this, for us, is this business called collaboration. And other useful things, I think, that are in the bill, organizational things--I think probably, Dr. Miller, you have done a lot of that over at your institute. Would any of you support this bill if it had level funding?

DR. FURCHT. That would be challenging.

MR. NORWOOD. So you are not interested in the other parts. You just want more money.

DR. FURCHT. No. I think there are better ways to use the money, which I think the bill covers; but we also need more money.

MR. NORWOOD. But if it didn't have more money, you wouldn't support it?

DR. FURCHT. No, there are some good things in the bill.

MR. NORWOOD. Good. All of you feel that way.

DR. KIRCH. If I may, one of the things that I think have been discussed at length is the fact that level funding, combined with creating a stronger Common Fund, would cause collateral damage to the current scientific base that none of us would want to see.

MR. NORWOOD. Dr. Kirch, I think we probably don't disagree with you there. I'm trying to find out if we had just simply given you more money, would that have satisfied everybody.

That doesn't satisfy this committee, I am sure, and I hope it wouldn't have satisfied all of you; because some of us think that part of this isn't just more money, but it is how the money is being used and is it being used, from the taxpayers' point of view, as wisely as possible.

Thank you, Mr. Chairman.

MR. UPTON. [Presiding.] Dr. Miller, did you want to answer that question?

DR. MILLER. I could not agree with you more. I believe you are correct, more money, but how you allocate that money and how you protect those young investigators. So I think those are crucial things.

Not that the other Institutes aren't doing great work, and we want those to continue, but we have to have ways to bring people together, and this is a mechanism to do that.

MR. UPTON. The gentleman from Illinois, Mr. Rush.

MR. RUSH. Thank you, Mr. Chairman. I want to ask all four of you basically three questions, but I want to preface my remarks with these four comments.

Eighty percent of NIH funds goes out to the private sector. In the area of diversity, there is no way to validate or determine the level of diversity among the private sector and clinical trials. It is also unknown to us what is the NIH oversight role over the private sector as it relates to diversity. Even though current Federal law requires inclusion of women and minorities in clinical trials, it still is a real issue that this committee and the American people face.

The three questions that I have for each of you:

Are there health disparities in clinical trials and otherwise, including researchers and also subjects?

The second question: Why is this so, if you agree.

And the third question is: What are your organizations--your schools, your medical schools, your universities--what are you doing about this blatant level of injustice as it relates to diversity issues in our Nation?

DR. MILLER. Start with me, I guess.

At Johns Hopkins, that has been a big issue. Johns Hopkins sits in an area of the city that is a very poor part of the city. We see a very diverse group of patients. It is part of all of our clinical studies that we have a very richly mixed group that are entered into our clinical trials. It is one of the elements.

It is a core value of Hopkins to be a diverse institution. We just recently adopted that.

And, lastly, we have the Urban Health Institute which looks at the community that surrounds Hopkins and tries to address the issues that you have raised in a very meaningful way across the School of Nursing, the Bloomberg School of Public Health, the School of Medicine and in the hospital and health system.

So I think we certainly understand your concerns. We are trying to address those concerns. We try to recruit faculty that will be able to help us move this whole process forward, and I think we have made real progress over the last 5 years.

DR. KIRCH. I would choose to focus on the question you asked regarding essentially the scientific workforce and its diversity. I think my colleagues are very prepared to speak to the way trials are conducted and studies are conducted.

The Association of American Medical Colleges has had this as one of its strategic issues for well over a decade. We have been working very hard to bring more underrepresented minorities into medicine and into science. It has, quite honestly, been a tough struggle, but we are slowly but surely making some progress.

I think this dovetails with one of the issues that has been discussed today, which is how important it is to support young scientists. If we can recruit them into careers in medicine and science, but then fail to provide them the early research support that they need and they leave medicine and science, that's a great tragedy and a great loss.

So we are continuing to work on that entire pipeline progression from before medical school and graduate school on out into the practice of medicine and the practice of science with a number of initiatives.

DR. ECKEL. Congressman, it is the law of the land that lack of diversification is unacceptable from a scientific perspective in terms of recruiting subjects into clinical trials. Every consent form that I develop that relates to the use of a medication or an experimental procedure in human subjects must include women, minorities, and children. The only reason that those types of individuals would be excluded would be on a scientific or medical basis. In other words, we are encouraged and work hard at trying to recruit minorities and other diverse populations in research.

Secondly, why does it exist? I share with you the theme of this being a political and social issue. The American Heart Association is very concerned about this problem. Since I was nominated and selected to be President-elect over 2 years ago, every board of directors meeting I have been to at the American Heart Association has included this topic for discussion, and there is proactive positioning of the AHA in this area of diversity.

We work hard through multiple mechanisms to enhance the diversification and retention of diverse staff and volunteers for the organization. In fact, our last volunteer leadership conference, held here in Washington last spring, dealt with diversity as a topic. So the AHA recognizes the issue and is attempting to solve this important problem.

DR. FURCHT. Congressman, I'm personally keenly aware of this.

A friend and colleague at Minnesota, a cardiologist, did a seminal trial that approved the first drug treatment for African American patients with hypertension and protecting them from heart failure. It was a landmark study. I think that we all must attend and be more acutely aware of these issues to remedy the past, and I think all of our organizations and individuals personally are doing that.

One thing that our organization, FASEB, is doing is that we have a special program called the MARC Program that is specifically designed

to attract and train minorities in biomedical research. This is a flourishing program. We are very proud of it, and we continue to hope that it grows, because it is by virtue of creating a workforce that is specifically interested in some of these problems that we will provide the long-term solution to the things you care about so much.

MR. RUSH. Thank you

MR. UPTON. Dr. Murphy.

MR. MURPHY. Thank you, Mr. Chairman, and it is really quite a delight to be in front of this distinguished panel here. I myself remain as an adjunct faculty member, which means the University of Pennsylvania doesn't have to pay me, but they can call me to lecture at any time at the School of Medicine and also the School of Public Health.

An area of key concern to me is how we get the Institutes to work together; and that is why this Common Fund, I am particularly excited about in some areas in particular. I know a lot of things that grab the news about what comes out of the Institutes are things in the molecular or genetic or the microbiological level of great discoveries. And yet, as we move from the lab bench to the hospital bed to the world at large, I consider it extremely important that we are taking these things and making sure they are applied to what we can learn, particularly about the aspects I mentioned before, about integrated care and about patient safety.

I would like comments from you as to how you see this bill as it is written, and what could be added to it and what could assist that flexibility. I am thinking in terms of this: that when we hear numbers--for example, that 70,000, 80,000, or 100,000 people a year may die due to problems with patient safety in hospitals; that we have \$50 billion a year wasted on infections that are picked up at hospital settings; when we recognize that people with heart disease have double the risk for depression and those who have untreated depression with heart disease, their medical costs are double.

Those are areas where tremendous knowledge can come out of integrating the research together at NIH to help work towards, how do we come up with practical solutions, as Congress has addressed this issue, with the cost of health care. I see this as an important part of NIH's mission, though not specifically spelled out, but I think it is an important part.

We, in Congress, are all deeply concerned on both sides of the aisle about people having healthcare be accessible and affordable, and we recognize that many people who are covered by Medicare and Medicaid, and community health centers--all things which this committee is passionate about working with--are important, but we also have to

recognize that 45 percent of the Federal mandatory budget is healthcare. We have spent a lot of money on that.

And our Nation, through bureaucracy, through paperwork and inefficiency, wastes a lot of money too. My estimate is between \$300 billion and \$500 billion that doesn't get to the patient, but is wasted somewhere else.

This is my only question, and I want to see some help on this, as to how you see this bill helping the Institutes work together towards integrating some of those aspects of care and improving patient safety.

Dr. Miller, can we start off with you?

DR. MILLER. Well, certainly the issue of patient safety has been high on everybody's radar screen for the past several years. One of the things we found at Hopkins over the past 4 or 5 years has been that you can drive it with research. That is, if you start to take some measurements and you take a look at what your infection rates, either catheter-related or surgical-site infections, or medication errors and so forth, and then really look at what the best practices are and how can you drive those numbers down to zero, there is a tremendous amount of research in that because it is not easily done.

I think we all kind of come to a certain point, and we can't drive it any lower; and then we find someone who has found some way to do it. So I think we can take some of these dollars and drive some of those initiatives to really improve the safety in the care delivery model.

One of the things you see in the care delivery model is the processes that are at fault. It is not the people. Therefore, you need to have a research protocol to look at those processes and make them better so that patients are not injured.

So I think there is a tremendous advantage to having, for instance, the Common Fund be able to direct some of those dollars and have Institutes work together. You can see where NCI, where one of the biggest issues probably is medication error in patients receiving chemotherapeutic agents, how can you minimize the chances that a patient will be injured by either getting the wrong dose or the wrong drug?

So I see a lot of advantages for that.

MR. MURPHY. Thank you.

Dr. Kirch.

DR. KIRCH. Well, I think your observation was right on target. If we simply focus on the molecular basis of disease, we can still have systems that fail on the other end. I think one of the real breakthroughs made by Dr. Zerhouni, when he first proposed the roadmap for NIH research, which this legislation really nicely dovetails with, was his vision of this spectrum. This transformation from the laboratory bench all the way out

to the health of the population, the quality of care, and the delivery system in which the care occurs. I think what this bill does is simply give the NIH a very well-defined tool to accomplish that.

I was very struck by one of the examples that you yourself gave in your earlier comments. So many of the diseases that burden our country in terms of pain and cost have strong behavioral components. So it isn't just understanding the molecular basis of those diseases. A disease such as obesity, it is understanding the social, environmental, and behavioral context in which they work. That requires multiple Institutes coming together.

MR. MURPHY. Thank you.

Dr. Eckel.

DR. ECKEL. I'd like to address the example you gave about depression and cardiovascular disease.

NIMH and NHLBI would both claim those areas, as they both have activities going on in the science and medicine of depression and heart disease. Yet, when this issue came up in a recent conversation on the Manuscript Oversight Committee of the American Heart Association, it was clear that the state of the art of depressive illness and heart disease really is not well understood.

So I will use that as an example of where the Common Fund, with appropriate oversight and coordination of activities, the NIH could be used to develop a question that has a research base that could ultimately lead to an answer. We don't know whether depressed patients who get antidepressant treatment show reduced risks for cardiovascular disease. Nor do we know if patients with heart disease who are deemed depressed, whether, once treated, experience a reduction in second events.

This is research, and I think the Common Fund could help solve that collaborative need.

MR. MURPHY. Dr. Furcht.

DR. FURCHT. Thank you. We, too, support the notion that the Common Fund can allow funding for nontraditional types of questions that have not been asked before. The Common Fund allows flexibility to address, in a more incisive way, questions such as patient safety and those relationships where different diseases or cures seem unrelated.

I am reminded of the anecdotal evidence with some of the nonsteroidal anti-inflammatories where patients are now seeing decreased cancer in those taking it chronically. Why does that happen? How was that not thought of?

So it is these types of investigations and answering questions such as you raise which are fundamental for all physician groups and clinical



practices and hospitals in the country relative to patient safety that I think the Common Fund would be allowed to address.

MR. MURPHY. Mr. Chairman, I think if they are able to show how they can save hundreds of billions of dollars through some of these things with the Common Fund, they will have earned a lot more money for NIH.

CHAIRMAN BARTON. [Presiding.] There you go.

MR. MURPHY. Thank you, Mr. Chairman.

CHAIRMAN BARTON. Mr. Green.

MR. GREEN. Thank you, Mr. Chairman.

Dr. Kirch, I am glad my colleague from Pennsylvania asked that question because I have some questions on the Common Fund also and suggestions in ensuring Common Fund research is subject to the same peer review standards as other NIH research. I have heard similar feelings from extramural grantees, who also want to ensure the peer review process under the Common Fund is equally rigorous for intramural as well as extramural applicants.

Can you speak to this issue with the perspective from these extramural grantees? And do you think report language will satisfy that concern, if that is possible?

DR. MILLER. I believe that the way it's written, and I don't know exactly, but it would seem to me there is enough safeguard and oversight of the use of those funds in the reporting relationship, especially at the 3-year period. I would imagine that any director who would use those funds would want to use an outside, or a group of experts inside and outside the institution to help that person decide, are those funds well spent or not?

MR. GREEN. But would they be subject to the same peer review as that in the legislation, that you know of?

DR. MILLER. I don't know the answer, but one of the strengths of NIH has been the peer review system. I think that's the one that we have lived by for years, and I think it has really done us well.

MR. GREEN. I would hope, Mr. Chairman, that is of a little concern, to make sure the peer review process covers the Common Fund.

And this question is for the whole panel. Since this legislation includes a new concept, such as the Council of Councils' Scientific Management Review Board, I want to make sure the makeup and the operations of these entities are balanced and appropriately reflect our scientific research needs.

While legislative text establishing the Scientific Management Review Board contains language ensuring the smaller institutes and centers, the text establishing the Council of Councils offers no such guarantee of inclusion by these smaller institutes. It's my understanding

the Council of Councils provision in the bill mirrors the way the advisory council is established under the Office of Portfolio Analysis and Strategic Initiatives.

Can any of the witnesses speak to their experience with that advisory council in this office currently? And moving forward, do you have concern about the inclusion of these smaller institutes and centers in the Council of Councils directing trans-NIH research? Is there any opinion on that, on the smaller institutes and the centers as compared to this large Council of Councils group, or compared to what similarly we have now?

DR. ECKEL. I would have to ask whether the language of the bill contains that information. According to your question, apparently it does not.

MR. GREEN. No, it doesn't. I guess the concern is, how is this under the current Office of Portfolio Analysis and Strategic Initiatives? And I would think, from the bill, that the Council of Councils is just a broader group for that. And, again, we don't want to lose some of our smaller initiatives in this umbrella group. Is there any concern of that? Have you had any concern on this?

DR. FURCHT. Well, it is an issue we at FASEB have discussed, but our hope is that with the balance of this Council of Councils, inside and outside, that you would achieve essentially the wisest decision when all is said and done.

It would be very difficult to represent every single interest group or institute or center director in such a process.

MR. GREEN. I know. I always said the best committee is a three-person committee, with me as Chair and somebody devoted to me as my second vote. But we need to make sure we have a broad representation, particularly from the smaller institutes, I guess.

DR. MILLER. We have no concerns.

MR. GREEN. Okay.

Mr. Chairman, that's all the questions I have. I appreciate the time.

CHAIRMAN BARTON. We thank the gentleman from Houston.

Mr. Shimkus, do you wish to ask questions?

MR. SHIMKUS. Thank you, Mr. Chairman. I am going to be real brief. I want to thank you for your testimony, the written testimony and also the answering of the questions. It is pretty exciting to see, to come this far, to a point where we are ready to move on the legislation. I think your responses have been very, very helpful to us.

And as I said in my opening statement, the issue on the common funding, which seems to be a current refrain, and addressing issues where the individual institutes and centers might have had challenges before, through this process. Because I think the older we get, the more

we know people with various diseases and maladies and illnesses; and we know that this research does cross over a lot of boundaries.

So I am very excited and very pleased with the testimony, and I think it just emboldens us to move sooner rather than later and get this show on the road.

So, Mr. Chairman, I just want to thank the panelists and yield back my time.

CHAIRMAN BARTON. The gentleman yields back.

In order of appearance, it would be Congressman Upton.

MR. UPTON. Thank you, Mr. Chairman, and I appreciate the opportunity to have this hearing and obviously will support the bill tomorrow as well.

Dr. Miller, I have just a couple of questions. One, I think each of us here has certainly health causes that all of us support and take a real interest in. One of them for me is cystic fibrosis, which you mentioned in your testimony when you indicated that a successful therapy has yet to be developed, yet we think we can find a cure.

And, again, I have met with a good number of folks involved in this particular disease, and I have seen the promise come about in the length of time that now someone, once they are diagnosed with cystic fibrosis, has the opportunity to live, I want to say it is double or even more than that in terms of years.

I just wondered how you think this bill will impact that cure really getting into all of the impacted lives that are out there?

DR. MILLER. Well, I share your concern especially with cystic fibrosis. When I went to medical school, life expectancy was 12 or 13, and now we are well into the 40s and 50s for some people. Having had a relative with the disease, who died at age 14, I know about this.

One of the things that I see, however, is that we have always been trying to look for the magic gene that is going to cure that patient. It looks to me like there are going to have to be other technologies brought in. So what is going to happen in bioengineering and how we can make new proteins to help fix the defect, these are areas that I think funds could be brought to address that issue, which have not, because we have been kind of working again in these silos. How do you bring in other people and say, listen, I have a problem and I can't figure it out; can I bring a bioengineer, can I bring a biochemist in, can I bring more people to solve the problem?

I think this is one of the ways it is going to happen.

MR. UPTON. Well, I was one of those, and I think it was a little more than 10 years ago that the debate began to double the funds for the NIH; and, of course, it was a very strong bipartisan effort that was successful in both the House and the Senate. And I would like to think that it is

because of that effort, things like the progress we have made in cystic fibrosis and others, that we have really come a long way and provided hope for those families and certainly the individuals that are impacted.

What other examples beyond cystic fibrosis might you be able to cite, for sure, that investment has done great things?

DR. MILLER. Well, I think if you just look in areas of oncology, I believe this is the first year in the United States that the death rate from cancer has fallen. I think that is a dramatic example.

I think issues that have been raised in terms of heart and lung disease are very impressive, and that would not have occurred. I think we can all remember what happened when someone had a heart attack a few years ago, compared to the therapies they have today.

What we are doing in the areas, admittedly oncology, but in terms of leukemia. My mother-in-law had lymphoma. That was a deadly disease. She lived for another 12 years after the diagnosis. That would not have happened.

MR. UPTON. And that's a good thing, right? That your mother-in-law lived another 12 years?

DR. MILLER. She was great. I knew her since I was 14, so, yeah, she was kind of like second mom. Yeah.

MR. UPTON. Just wanted to make sure.

DR. MILLER. I think there are multiple, multiple examples out there where the doubling of the NIH has made a true impact on the health of this country.

MR. UPTON. Yes, Dr. Kirch?

DR. KIRCH. If I may, one of the things that always concerns me is, if we as a society expect things to change overnight in terms of dealing with these tough, tough diseases, we make a mistake. Change is step-wise and progressive, but that change can be huge.

When I started medical school, 80 percent of children with leukemia died. Today, 80 percent of children with leukemia go on to have a full life. That is transformational, but it didn't happen all at once. It was a series, over the years, of steps forward. And we have seen that in many other areas of science.

Everyone at this table thought in the early 1980s that our hospitals today would be bursting at the seams with terminal AIDS patients. We haven't cured AIDS, but we have found some very, very effective treatments.

MR. UPTON. Dr. Furcht.

DR. FURCHT. Yes, if I might comment on the utility of the Common Fund and these trans-NIH initiatives by another example, in the late 1970s and 1980s there was a specific program at NIH called the Special Virus Cancer program, trying to find the virus that caused cancer. Well,

that was or wasn't found, but what has come out of that is that in studying animal cells that were infected with different cancer viruses, it was found that they produced factors that made blood vessels grow, that made the cells grow, whatever; and today we now have drugs in the marketplace that patients are getting that are based on discoveries made while studying tumor viruses in mice or chickens. So how could that have been planned at the time?

And it is the ability to have this flexibility that this bill will promote that I think will allow who knows what in the next 10 to 20 years as far as new therapies for patients.

MR. UPTON. I think that underscores the need to get this bill done. And from every discussion that I have had, I think it is clearly going to be bipartisan; and I look forward to its passage in full committee tomorrow and on the floor as early as next week. And I commend Chairman Barton for working with both sides of the aisle and with our colleagues in the Senate to try to get this thing done, because I really do think it will make a great difference.

CHAIRMAN BARTON. The gentleman's time has expired.

Congresswoman Blackburn.

MRS. BLACKBURN. Thank you, Mr. Chairman, and thank you to all of you for your time and for being here.

I am not a physician like Mr. Murphy or Mr. Norwood, or Mr. Burgess, who sits beside me, but I am one of those who has been a volunteer and a board member for a children's hospital and a lung association and a cancer society and arthritis, and--as my husband always says--disease efforts, and putting time and energy into raising money.

One of the things we always learned through that was the importance of accountability and the importance of the public being able to know that, as we went to them and raised funds, we were accountable and we were going to do good things and put our aim on giving a good product and serving the community.

As we have worked through this situation with NIH in the hearings and looked at legislation, the accountability factor continues to come up time and time again. And we have held some hearings recently, the Oversight and Investigations Subcommittee has held some hearings, on some of the ethics problems with NIH researchers. And even though we have doubled the NIH budget for years, the tentacles of those ethics problems, as deeply seated as they seem to be with NIH--it does a lot to undermine the faith that the public in general has of the NIH.

I have found it to be very unfortunate, because I am one of those that likes to see you all make strides--not just steps but strides--when it comes to medical research and answering problems. And having lost a mother-in-law to Alzheimer's, I have found it very unfortunate that part

of the ethics breaches that we experienced dealt with that research. It is really an unfortunate thing to happen.

But just a quick yes or no, do any of you think that we should have some provisions in the bill that would prohibit similar ethics breaches? And you may not have followed the hearings we have done; you may have.

Dr. Furcht, looks like you have.

DR. FURCHT. Yes, I am keenly aware of that; and if I could give you a little bit more of an extended answer, but not long--

MRS. BLACKBURN. Very quickly.

DR. FURCHT. --we think this is extremely important. I don't believe it needs to be part of the bill.

MRS. BLACKBURN. Would you support it as a separate bill?

DR. FURCHT. Potentially. We are coming at this in a different way. Our organization is leading a coalition, AAMCAAU and others are beginning to work with us where we want to establish common national standards relative to research, ethics, conflict of interest in research, et cetera; and we are hoping to move that forward. We actually have a grant to work on that.

MRS. BLACKBURN. Okay, so you would favor it through the rulemaking process as opposed to through legislation?

DR. FURCHT. Correct.

MRS. BLACKBURN. All right.

Anyone else with a quick comment on that?

DR. MILLER. I agree with that approach. As a matter of fact, Dr. Kirch and I are going to Cleveland tonight to spend all day talking about conflict-of-interest issues in biomedical research. We think it is very important.

I think one of the problems is that not one size fits all problems. And I think you have to look at when is the public good going to be benefited by moving products forward from the basic research into the business world. And how is that going to occur, and what kinds of conflicts might surround it versus ones where the market might be manipulated and some bad things can occur?

So it is a difficult issue, and it is one, I think, we are all wrestling with.

MRS. BLACKBURN. Okay, thank you.

I have one other quick question I want to pose to you all. The bill does establish a reporting system, but we know this is fake, within the bill. And one of the things that has come up as we have gone through the hearings is access to information, being certain that when research has been done, that the information is catalogued, or that papers are written,

and that there is a way for that to be picked up and carried on so that it does not drop.

One of the things that had come up, had been mentioned by some folks that are out of Tennessee where I am from--I represent some of Memphis, some of Nashville, and a lot of area in between--would be for papers to be submitted--when they are done with federally funded research, papers to be submitted and then those papers made available on a free public database.

Would any of you have a problem with that? Anyone care to answer?

Dr. Miller, go ahead.

DR. MILLER. This would be before the paper has been reviewed, peer reviewed?

MRS. BLACKBURN. Yes, and I understand what you are saying, the verification process of that.

DR. MILLER. You know, if someone sets up an experiment and they give an answer that says "yes" or "no" and the experimental design is wrong, you can't believe the answer.

So peer review would kind of say, that design is appropriate, they did the data, they collected the patients at the appropriate rate, the numbers were appropriate, and the conclusions they raised were valid.

If it goes in without that, it is just meaningless data.

MRS. BLACKBURN. Okay. Sometimes I know, as we have found from some of our global warming research, that the community of scientists that handles that peer review can be very difficult, too, and can also color how people--anyone else with something to say?

CHAIRMAN BARTON. The gentlelady's time has expired.

MRS. BLACKBURN. I am out of time, and I thank you, Mr. Chairman.

CHAIRMAN BARTON. Mr. Terry.

MR. TERRY. No questions.

CHAIRMAN BARTON. Mr. Deal.

MR. DEAL. Thank you, Mr. Chairman. I want to apologize for not being here to hear your testimony, but I was on the floor handling some health-related resolutions, and we passed about four of them just a minute ago. One of them dealt with the goal of achieving a conquer over cancer by the year 2015, which, of course, is a goal that all of us would like to see achieved. I am hopeful that what we are doing here in this reauthorization, as well as reorganization, of the NIH will assist in that endeavor.

I really don't have any questions to ask of you. I just want to thank all of you for being here.

And I want to thank the Chairman for his dogged persistence in moving this issue forward. It would not be where it is had it not been for his insistence that we do something in what I think all of us consider a very important area.

And, also, I want to thank the staff. They have worked extremely hard to bring this issue forward.

And thank you, gentlemen, for being here today.

And I yield back, Mr. Chairman.

CHAIRMAN BARTON. Almost like a Georgia Bulldog, you might say.

Well, I want to thank you gentlemen and I want to thank your organizations. This is a historic moment. We are going to have an open markup tomorrow. Obviously, there are going to be members that offer amendments, but I think the base bill is a very good work product, and it is because of your willingness to cooperate on behalf of your organizations with our committee staff and Mr. Dingell. So I do congratulate you and I look forward to working with you in the next several weeks.

With that, we will release you. I know some of you have a plane to catch. I know, Dr. Miller, you do. So we want to bring the Director of the NIH forward, Dr. Elias Zerhouni.

Welcome again before the committee, Dr. Zerhouni. It goes without saying that you are a valuable member of the executive branch and have done an excellent job in managing the NIH. We appreciate you and your staff's comments on the various drafts of the bill.

We want to recognize you for such time as you may consume to comment on the draft, and then we will have some questions. But welcome once again to the committee.

#### **STATEMENT OF DR. ELIAS A. ZERHOUNI, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

DR. ZERHOUNI. Thank you, Mr. Chairman, and members of the committee. I am Elias Zerhouni; I am the Director of the National Institutes of Health, and I am here today at your request to testify about the legislative reauthorization of NIH.

Interestingly enough, the current reauthorization proposal will be only the third omnibus reauthorization of NIH since enactment of the Public Health Service Act in 1944. Omnibus reauthorizations occurred in 1985 and 1993, and those previous acts primarily extended the number of institutes and centers at NIH, concentrating on specific diseases, organ systems, and special populations.

Throughout the periods of budgetary and structural growth, NIH truly drove the biomedical research engine of our Nation toward



unprecedented scientific discoveries that have fundamentally changed public health. For example, our success in addressing acute illnesses has shifted the landscape of disease. Today, our population suffers more from chronic and more manageable diseases that account for over 75 percent of our healthcare expenditures.

The key transformation underlying all of these changes, as you have heard from the prior witnesses, has been the convergence of science. Scientific concepts have become more intertwined across all diseases and conditions. As we have learned more about the molecular causes of diseases, we have found great similarities between the mechanisms that lead to diseases once thought unrelated. You just heard an example for research on viruses and cancer which found application in AIDS treatments.

Often research in one field finds unexpected application in another. The greatest research advances of recent years involve the fields of molecular and cell biology, as well as genomics and proteomics, among others. But their applications will not be limited to specific diseases or populations. They will be applied to all diseases and all populations, and that will require greater interdisciplinary efforts.

NIH strives to encourage these new ways of conceptualizing and addressing scientific questions and to encourage their translation from the laboratory to the clinic. Already, as you have heard probably from the other witnesses, such approaches are yielding a trove of discoveries, from mental disorders to cancer to prevention of AIDS-related blindness, as examples.

We all have great expectations for the advancement of biomedical research in coming years, but the question members of this committee have consistently asked me, repeatedly over the past 4 years, is: Does the current structure of NIH allow the more multidisciplinary and collaborative approach to science required to meet these expectations? Is the structure that has emerged from the past 50 years tending in any way to impede good function? I think this is the central issue that this bill addresses extremely well.

I think there is no doubt that science will require more collaboration and more interaction. And, in fact, as we understand more about life processes, we also understand that overlap between concepts, between mechanisms, is more likely to happen in the future. And the boundaries between the specific science and mission areas of the institutes and centers are increasingly blurred and now require more interaction.

Today, in addition to that, public health has changed. Patients often suffer from more than one disease at a time, creating the need for greater coordination of care, as well, in our population. And I have to say that our institutes and centers, their directors, have increasingly worked

collaboratively whenever appropriate. And, clearly, I think NIH through the past several years has taken advantage of the breakthroughs that were made, thanks to the support that you have provided NIH; and we are clearly showing the results in terms of exploiting the human genome that was completed in 2003, as well as the new research that identifies the common causes of very complex diseases.

Nonetheless, better mechanisms of functional integration that enhance synergy across all of NIH need to be found. I believe that the proposed bill serves this purpose by preserving to the largest extent the autonomy of the institutes and centers, while creating a Common Fund and a shared, transparent mechanism for addressing issues that no single institute or center can address.

Over the past 4 years, NIH has experimented with ways to accomplish these goals by implementing a series of initiatives, such as the Roadmap for Medical Research, the NIH Plan for Obesity Research that integrates the efforts of about 21 Institutes, and the Neuroscience Blueprint that integrates the efforts of all of the institutes that have an interest in the brain, mind and behavior.

All of these initiatives are really designed to take rapid advantage of the enormous progress, but what we need is really a flexible process that allows you to take advantage of emerging opportunities or public health problems without going through a protracted mechanism of give-and-take, if you will, especially as we are facing constrained budgets.

Actually, one scientist put it to me in a very tangible way. He said, Imagine that the human genome project came up today when the NIH budget is flat. Would we find a mechanism to fund the human genome project when you have constrained budgetary times? And the issue is, without such a mechanism, functional integration, collaborative research, the promotion of new ways of doing research, and taking advantage of unique opportunities will be hampered.

So this is why I think that the proposal that you have put forward avoids, in my view, a bureaucratic top-down process and preserves objectivity by relying on the time-honored NIH system of peer review and evaluation, which I think should be preserved and defended, because I think it allows a transparent process of priority-setting, but also makes sure the best science is funded.

I strongly urge the committee to also ensure that the growth of the Common Fund be tied to increases in the NIH in your appropriation. I cannot tell you how difficult the situation is currently, and I know that you have been extremely generous in doubling the NIH budget. Yet, at the same time, I can also tell you that the institutions around the country

have made enormous investments in increasing the research capacity of our country.

For example, today we receive twice as many applications as we did before the doubling, and each application, because of inflation, is 40 percent more expensive. The competition for funds is greater than ever.

Success rates prior to the doubling and during the doubling were above 30 percent; today they are below 20 percent, and my concern is that new investigators, new scientists will come forward and embrace the challenges that we all face and need to be supported. I think it is very important, therefore, not to deviate from supporting these activities through a Common Fund and essentially take it from current programs.

The proposal also tracks, I believe, the IOM recommendations, including establishing a formal process for reorganizing offices and programs, standardization of data and information systems at NIH. I think that the pursuit of scientific opportunity is best served through investigator-initiated grants, which have been and should remain the mainstay of our research-supported mechanisms.

Balance in the portfolio of the entire NIH is what we need, and addressing emerging issues, whether in public health or in terms of scientific opportunity or maintaining a vibrant workforce, such as new investigators, are all purposes that the Common Fund should be open to. I believe strongly that free exploration of ideas generated by the scientists themselves has been and will continue to be the key to our long-term success.

I think the fundamental vision of NIH in the 21<sup>st</sup> Century, going forward, is that we hope to transform medicine and health from a curative paradigm, where we waited for a disease to strike the patient before we intervened; I think the progress we have made over the past 10 years lets us envision a completely new world where medicine will be predictive and personalized and preemptive. This is what we call the three Ps of the future of medicine. And I think NIH is strategically positioned to do that and is investing in research where we could identify and predictably tell patients what diseases they are at risk for, personalize the treatment that we need to implement, and hopefully preempt rather than treat disease, which will be orders of magnitude more effective than what we are doing today.

I believe that our vision, which is to transform medicine and health through NIH-supported discoveries, is probably the only hope that we have of greatly reducing healthcare costs in the future.

This concludes my testimony, and I will be pleased to respond to any questions, sir.

[The prepared statement of Dr. Elias A. Zerhouni follows:]

PREPARED STATEMENT OF ELIAS A. ZERHOUNI, M.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Chairman Barton and Members of the Committee. I am Dr. Elias A. Zerhouni, Director of the National Institutes of Health (NIH), and I am here today at your request to testify about the legislative reauthorization of NIH. The current reauthorization proposal would be only the third omnibus reauthorization of NIH since enactment of the Public Health Service Act in 1944. Omnibus reauthorizations occurred in 1985 and 1993. Those previous acts expanded the number of Institutes and Centers at NIH, concentrating on specific diseases, organ systems, and special populations.

As a result of such structural growth and appropriation increases, highlighted by the doubling of NIH's budget between 1998 and 2003, the NIH is a far different organization than it was 13 years ago, when Congress last reauthorized Title IV of the Public Health Service Act. Our budget is nearly \$29 billion. We have over 17,000 employees.

Throughout its history, NIH drove the biomedical research engine of our Nation toward unprecedented scientific discoveries that improved public health and fundamentally changed the nature of medicine as well as the burden of disease. Our success in addressing acute illnesses has shifted the landscape of disease from once acute, severe, and lethal conditions to more chronic and manageable conditions.

However, as the Institute of Medicine observed in 2002, "While NIH's success is to be celebrated, success alone does not answer fully the question of whether there is a better way to proceed, particularly as one faces a future where the world of biomedical sciences is being rapidly transformed in all its dimensions."

The key transformation has been the convergence of scientific concepts, approaches, opportunities, and needs across all diseases and conditions. As we have learned more about the molecular causes of diseases, we have found great similarities between the mechanisms that lead to diseases once thought unrelated. Often, research in one field finds unexpected application in another. The greatest research advances of recent years involve the fields of molecular and cell biology as well as genomics and proteomics, among others. Their applications will not be limited to specific diseases or populations. They will be applied to all diseases and all populations. This will require greater interdisciplinary efforts. NIH strives to encourage these new ways of conceptualizing and addressing scientific questions and to encourage their translation from the laboratory to the clinic. At the same time, we work towards increasing our understanding of the behavioral and social sciences necessary to insure the success of biological approaches to health and disease.

For example, the convergence of science underlies the new Genes and Environment Initiative in NIH's FY 2007 budget request to Congress. This is a project designed to address a broad array of health and disease concerns and will build on advances in multiple areas of science, including genomic sequencing technology and environmental science. It will give us the unprecedented ability to discover the potential causes of the 10 most common diseases afflicting the U.S. population. Already such approaches are yielding a trove of discoveries in areas from mental disorders, to cancer, to the prevention of age-related blindness.

We have great expectations for the advancement of biomedical research in the coming years. The question now being asked by Congress, the scientific community, medical providers, patients, and NIH itself is: does the current structure of NIH allow the multi-disciplinary and collaborative approach to science required to meet these expectations? In this era of enormous potential and scientific convergence, how does NIH best adapt?

Fundamental science has rapidly evolved due to recent advances in new fields such as genomics, proteomics, and many other breakthrough discoveries. The boundaries between the specific science areas of each of NIH's 27 Institutes and Centers (ICs) are increasingly blurred and now require greater interdisciplinary interactions. Our population faces chronic and complex diseases, which now account for over 75% of healthcare expenditures. Patients often suffer from more than one disease at a time affecting multiple organ systems, mechanisms, and life stages, creating the need for greater coordination. In many ways, ICs have already responded and are working together whenever appropriate.

Better mechanisms of functional integration that enhance synergy across all of NIH need to be found. Some provisions in the proposed bill serve this purpose by creating a common and shared mechanism for addressing issues that no single IC can address, and providing opportunities for ongoing formal review of the structure of NIH through input from IC Directors, scientific advisors, and other stakeholders. Over the past 4 years, NIH has experimented with ways to accomplish these goals by implementing a series of trans-NIH initiatives such as the Roadmap for Medical Research, the NIH Plan for Obesity Research, the Neuroscience Blueprint, and many other initiatives, all designed to take rapid advantage of the enormous progress made during the doubling of the NIH budget. Establishing these formal mechanisms of integration gives NIH a great opportunity to build on its remarkable success to date.

The bill under consideration fosters interdisciplinary research and strategic planning by establishing an organization to integrate the work of the ICs through the identification of trans-NIH research programs that will broadly impact all areas of research. Further, the bill would create a funding mechanism – a common fund for shared purposes – for greater coordination of NIH research, whenever appropriate, as determined through an open and collaborative consultation and advisory process involving all relevant stakeholders. This fund is in conformity with the Common Fund for shared needs that NIH has already established to support trans-NIH initiatives, as discussed below. The bill preserves the time-honored NIH system of peer review and evaluation.

I believe the current proposal will preserve such vital authorities as peer review and the pursuit of scientific opportunity through investigator-initiated grants - which have been and should remain the mainstay of our research support mechanisms. I believe strongly that free exploration of ideas generated by the scientists themselves is the key to our long term success. Human subjects protections, and the requirement to disseminate research findings to the public will remain, as in our current authorization. I think the Committee is focused on organizational efficiency and effectiveness, which is the principal challenge for an increasingly large and complex organization.

This bill creates a central planning and analysis division for trans-NIH research within the Office of the NIH Director. NIH has recently established such an office through administrative mechanisms. It will be instructive to the Committee to share NIH's vision for the function of this new organization.

The mission of the new Office for Portfolio and Analysis and Strategic Initiatives (Office) is to provide NIH and its constituent ICs with the methods and information necessary to manage their large and complex scientific portfolios, to identify – in concert with multiple other inputs – important areas of emerging scientific opportunities or rising public health challenges and to assist in the acceleration of investments in these areas. Bringing together these diverse components of the agency will facilitate “functional integration” of NIH in a time of unprecedented scientific opportunities. It will help the agency to increase its effectiveness and efficiency in advancing science, ultimately resulting in the acceleration of basic research discoveries and speeding the translation of those discoveries into applications that improve the health of the American people.

The Office will accomplish its mission through the activities of three divisions and an office of the director. The mission of the Division of Resource Development and

Analysis (DRDA) is to employ resources (databases, analytic tools, and methodologies), and to develop specifications for new resources, when needed, in order to conduct assessments based on NIH and other databases in support of portfolio analyses and priority setting in scientific areas of interest across NIH. DRDA will also be a resource for portfolio management at the programmatic level, should individual ICs request the Division's expertise or tools.

The Division of Strategic Coordination (DSC) is responsible for integrating information and managing the process by which recommendations are developed to inform the priority-setting and decision-making processes of the NIH in formulating trans-NIH strategic initiatives. These initiatives will address exceptional scientific opportunities and emerging public health needs. The DSC will provide the Director with the information needed to allocate resources effectively for trans-NIH efforts. Although the new office will not have grant-making authority, the DSC will provide an "incubator space" for trans-NIH initiatives, and support priority projects on a time-limited basis (generally 5 years and not to exceed 10 years). This will support continuous development of new, trans-NIH efforts adaptive to public health and scientific opportunities and issues through all available mechanisms, including individual investigator-initiated research grants as determined by scientific consultations. Support will come from pooled resources (the Common Fund).

The Division of Evaluation and Systematic Assessments (DESA) will plan, conduct, coordinate, and support program evaluations, including, but not limited to, Institute and Center-specific program and project evaluations; evaluations of trans-NIH activities, including Roadmap initiatives; and systematic assessments, such as those required by the Government Performance and Results Act (GPRA) and the OMB Program Assessment Rating Tool (PART). The functions of DESA will allow for strategic planning and the coordination and evaluation of the NIH research agenda and portfolio and provide essential information for determining NIH-wide resource allocations.

The Office will make use of a "Common Fund" for shared NIH needs. The Common Fund is an annual set-aside fund created from an agreed-upon percentage of the annual budgets of each of the NIH ICs to support activities/efforts identified by the Office. Office operations will not be funded out of the Common Fund.

Stakeholders, including the scientific and advocacy communities, will be invited to submit ideas for new initiatives on a regular basis. These nominations will be considered by the NIH leadership, external consultants, IC Directors, representatives of IC advisory councils, and other advisory councils. Once a new initiative is approved, it will be assigned to a lead IC for further development and administrative oversight. Funds from the Common Fund will be used to support the initiative. The progress of each initiative will be subject to rigorous review. There will be an annual review of progress and a major review at year 3-4 that will determine, not later than year 5, whether to renew the initiative for a final 5-year period, continue the research but transfer support to a more appropriate Institute or Center, or complete the initiative. No initiative will remain for more than 10 years, thus insuring the long-term flexibility and vitality of this approach.

I remind the Committee that Title III of the Public Health Service Act authorizes the Secretary of Health and Human Services to use the Public Health Service to "encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man . . . ."

Over the past 50 years, the achievements of NIH and our academic and industry partners in medical research are nothing short of remarkable. According to the latest report on the Nation's health from the Centers for Disease Control and Prevention (CDC), life expectancy continues to rise, now at an unprecedented 78 years for the total

U.S. population. Since 1950, the age-adjusted death rate for the total population declined by a remarkable 43 percent. Life expectancy has increased by one year in every five for the past 30 years. Americans are not only living longer, they are healthier. For instance, the disability rate of American seniors dropped by almost 30 percent in the past 20 years, owing to a range of scientific advances.

In the past 30 years, death rates of two leading killers, cardiovascular disease and stroke, have declined by 63 percent and 70 percent, respectively. Such medical breakthroughs as drug-coated stents, therapies to achieve safe levels of blood pressure, and cholesterol lowering drugs have cut the expected number of deaths from heart attacks this year by more than half. In the past year alone, more than a million lives were saved.

For patients affected with AIDS, the development of highly active antiretroviral therapy (HAART), the result of work performed by a cadre of NIH-supported scientists and their counterparts in industry, has transformed AIDS into a manageable disease, preventing hundreds of thousands of hospitalizations and early deaths. The advances have had a particular impact on children. Today, fewer than 50 HIV-infected babies are born each year in the United States, sparing 16,000 to 20,000 infants from mother-to-child AIDS transmission.

This year, for the first time in history, the absolute number of cancer deaths in the U.S. has decreased. We now have ten million cancer survivors. We can detect and treat cancer at earlier stages. Targeted therapies have emerged, using specific molecular targeting to treat tumors with new agents. NIH's National Cancer Institute and others have identified biomarkers of cancer, foreshadowing an era when the disease can be predicted before symptoms appear, and treatment can be effectively targeted and personalized to the individual cancer patient.

For the first time in history, scientific progress allows us to hope for a revolutionary era when medicine will move from being **curative** and inherently costly in nature to become **predictive, personalized, and preemptive**. Toward this goal, NIH is strategically investing in research to further our understanding of the fundamental causes of diseases at their earliest molecular stages so that we can reliably **predict** how and when a disease will develop and in whom. Because we now know that individuals respond differently to environmental changes according to their genetic endowment and their own behavioral responses, we can envision the ability to precisely target treatment on a **personalized** basis. Ultimately, this individualized approach, completely different than how we treat patients today, will allow us to **preempt** disease before it occurs with the hope of reducing future healthcare costs. Our vision is simply to transform medicine and health through accelerated discoveries.

This concludes my testimony. I will be pleased to respond to any questions Members of the Committee have.

CHAIRMAN BARTON. Thank you, Dr. Zerhouni. I am going to recognize myself for the first 5-minute questioning period.

As a Presidential appointee and the Director of the NIH, are you allowed to endorse specific bills?

DR. ZERHOUNI. Unfortunately not.

CHAIRMAN BARTON. Okay. If you were allowed to endorse specific bills, what would your tendency be on this particular bill if you were allowed to do something like that?

DR. ZERHOUNI. As I said, I think the bill addresses some issues that not only I, but many in our community have felt over the years, that NIH is an outstanding institution, that there is nothing broken. The structures

of NIH have served us well. But science has evolved, and I think that rigid structures that stand in the way of better function are things you would want to reexamine, and I think your bill is doing that.

CHAIRMAN BARTON. Okay. Could you comment on the current system, or lack thereof, at NIH about coordinating across the institutes the different inventories and the different reporting systems and information systems with what is in the pending draft bill?

DR. ZERHOUNI. Right. This is an issue that the institute directors and myself have grappled with.

And, actually, 2 years ago the institute directors and I realized that because of the complexity of NIH today, as compared to its complexity 10 or 15 years ago, it is really important to have modern information systems to be able to accountably understand what is being done among the different entities of NIH. So having this common standard, a common way of reporting, of analyzing our research, we feel is something that the agency needs.

In addition to that, I think it will simplify our interaction with the oversight functions of Congress and all of the other issues that you face in interacting with our agency and providing a very effective and common interface, if you will, between the agency and the stakeholders that will increase the transparency.

So we are in favor of that, and the IOM also recommended that we do something about that.

CHAIRMAN BARTON. One of the things that the NIH prides itself on, justifiably, is its peer review system. Is there anything in the draft bill that compromises or weakens the peer review process currently in place at NIH?

DR. ZERHOUNI. I am not aware of that. And I would say no matter what we do, we need to preserve that system. It has served us well.

CHAIRMAN BARTON. With regard to the implementation of this Common Fund, do you believe that the peer review process will function compatibly with the Common Fund?

DR. ZERHOUNI. Oh, absolutely. I think there should be no exception to programs or initiatives at NIH that do not go through the filter of peer review both at the concept stage--before you even ask for people to apply or encourage people to apply, you need to have what I will call "transparent checks and balances," having enough advisory structures that are open to both members of the scientific community and the public--like a Council of Councils, multiple consultations. So that is before you even start a program.

And then, when the program is launched, I think we need to absolutely have independent peer review for each one of them.



CHAIRMAN BARTON. Mr. Waxman, in his questions to the first panel, was concerned that, under current law, the HHS Secretary and the Director had the ability to unilaterally make changes in the structure of NIH without congressional oversight. Would you care to comment on your authority under current law, and the HHS Secretary's, and also whether the draft before us provides more public input and transparency to any institutional changes that might be considered?

DR. ZERHOUNI. I am not familiar with the details of the current law, but it seems to me that the fundamental law is not changed. In other words, the authorities exist already for creation of a center, removal of a center with the secretarial input. This is part of the last reauthorization of the NIH, I believe, started in 1985 or at that time, I believe.

I think that what the new bill does, which is something that the Institute of Medicine has been recommending, is to create an explicit process. Because even though it is in current law, NIH directors have been reluctant to use that. Remember that almost every institute and center has been created through congressional action, not NIH action, except perhaps with the Human Genome Institute and a couple of the centers.

What my understanding is is that you are really creating a more transparent public process that will allow consideration on a regular basis of the structure of NIH, which hasn't really happened in the past because, as you well know, between last year and this year you have felt the pressures of constituent groups in terms of not losing structures, and we really need an independent, arm's-length process--

CHAIRMAN BARTON. The draft does freeze a number of institutes at what is currently authorized, which I think is currently 27. Is that a good idea or a bad idea?

DR. ZERHOUNI. In my view, it is a good idea. I don't think institutes that go from a \$5 billion institute like National Cancer Institute to the Fogarty International of \$67 million of budget with very important missions--I think there is a limit to the number of units you can create without losing efficiency.

CHAIRMAN BARTON. And then my final question before I recognize Mr. Waxman. Given your answer to that question--which I agree with, by the way--we have right now before the committee five or six pending bills that are specialty bills for various disease-specific groups or organ groups, and they all have legitimate concerns. I think they are sincere, and I think they address needs that need to be addressed. How do we integrate these new concerns, new diseases or prioritize existing disease groups or organ groups that currently don't have their own institute within this framework?

DR. ZERHOUNI. First, I would not go along with creating new formal authorized structures with their own administration and duplication essentially. I think we need to find ways through the functional integration mechanism that we are talking about to make sure that the two issues that I often see are, one, a disease that is overlapping with multiple institutes where there is a sense that coordination and integration is not happening. There are dozens of bills that contain language that instructs the NIH to have coordinating committees for this and coordinating committees for that. That is very important. It is a good mechanism. I think it is better to do it functionally than to do it in a new structure.

CHAIRMAN BARTON. Okay, thank you, Doctor.

Mr. Waxman.

MR. WAXMAN. Thank you, Mr. Chairman.

Dr. Zerhouni, good to see you again.

Under this bill, NIH will have a sizeable Common Fund in the Office of the Director that supports trans-institute research. Is it your understanding or intent that grants from the Common Fund would be made from the Office of the Director? Would you operate like another institute? Or would you expect the individual institutes to actually make the grants?

Also, I wonder if you would elaborate on how peer review would be carried out. Does the Council on Councils actually do the peer review?

DR. ZERHOUNI. Mr. Waxman, what I think is very important to go back to is that the Common Fund--no initiative in the Common Fund is supposed to be permanent, but every initiative will last 5 years, at most 10 years. The Common Fund is really an incubator for new ideas to support public health needs that are not addressed; and, therefore, the idea that the Office of the Director would grant grants is not a good idea, in my opinion.

I think what should be done is identify the areas where there are gaps in the portfolio. The Council of Councils role is really to prioritize those. Because even though you think it is a large fund, it is only 5 percent of the NIH budget, if it gets there, given our budgetary constraints; and, therefore, I think it is important to have the Council of Councils identify the priorities and suggest what programs should be funded. But once that is decided, institutes that are most relevant to the area should really grant the programs and use the same peer review as they currently do.

MR. WAXMAN. The Chairman's bill requires that every 2 years you submit reports describing the research activities at NIH to Congress. Much of the report would be a simple listing or a category of the grants that are ongoing research conducted and supported by NIH.

However, the bill would also require that you compile extensive descriptive information regarding the studies. For example, for research on specific diseases, you would be required to submit a statement of objectives regarding the research, the means for achieving the objectives, and a date by which the objectives are expected to be achieved and justifications for revisions for the plans.

I certainly see the value of having widespread access to this kind of information. But I want to make sure that, in the way we are asking for it, we haven't given NIH an impossible or overly burdensome task. Could you comment on that?

DR. ZERHOUNI. The potential is there to create an overly onerous task if the current reporting structure is not also lightened enough for us.

I think what we are trying to do here is really to create an interface where the reporting will be more transparent and easier to get from the various parties that are interested in it. But the issue that you have in reporting is often overlapped between, for example, pediatric cancer. How do you account for this? Is it a pediatric disease or a cancer investment? And often this is a difficult situation to resolve.

However, I think that putting measures--metrics on research is unwise in my opinion in the sense of saying, you know, when is it that you are going to find a cure for cancer.

MR. WAXMAN. So you would prefer a less burdensome process.

DR. ZERHOUNI. Yes.

MR. WAXMAN. Under the bill, the Director is charged with approving all clinical Centers of Excellence recommended by the National Research Institutes, other than NCI. Do you consider this to be a new authority, and how does this provision change how the Centers of Excellence operate today?

DR. ZERHOUNI. That issue came up because of the proliferation of centers and the fact that it is very hard, once you have a center, to really move away from that even though the science may have moved.

I am concerned about centers because, as I have told you, investigator-initiated research is really important. Centers really consume a significant amount of resources without necessarily serving all of the purposes that we would like them to serve at all times. So institute directors and myself have been talking about how do we make sure that there is a second level of review when you are going to create Centers of Excellence, which by their nature almost never sunset.

MR. WAXMAN. Is this a new authority, then, as you see it?

DR. ZERHOUNI. I think it is not in the previous authorization, yes.

MR. WAXMAN. As I understand it, 50 percent of any increases and appropriations over and above the preceding fiscal year would be required to go into the Common Fund, but it looks like the Director has

the discretion to take these funds from any of the accounts at NIH. Is that your understanding and would you favor some guidance on where the funds for the Common Fund should be taken from? For example, if we said that the funds should be taken proportionally from a specified set of accounts? Or would it be better and easier if the appropriator simply directly appropriated into the Common Fund account?

DR. ZERHOUNI. I think the current design is a set-aside percentage from the budget of every institute so that there is, in fact, a shared Common Fund. This isn't an extraneous fund that is directed without participation by all the institutes. You really need that sense of coming around the table.

In terms of technical execution, what we find is because the Common Fund does not grant its own grants and that we--because we allocate that to service specific institutes for execution, we need the flexibility to moving the Common Fund to that institute whenever needed. So I don't now have a preference one way or the other, as long as it doesn't lose that functionality.

MR. WAXMAN. The existing law seems to give the Secretary and the Director the ability to abolish institutes, to change the structure right now, but that has never been used. You indicated when Congress adopts a provision that there be an office, let's say, on women's health or other purposes that you have respected it or your predecessors have respected it and never invoked that authority. This bill gives a very specific authority to make these changes without Congress approving them. It sets out a process, but it isn't a recommendation to Congress. It is advising Congress that this is going to be done unless Congress reverses it. Is that what you intend because you want the authority you don't think you have?

DR. ZERHOUNI. Well, first of all--

MR. WAXMAN. Or do you think you ought to have your recommendation first?

DR. ZERHOUNI. Well, first of all, I think the authority that you are referring to is in current law; and the fact that it has not been used is because there hasn't been a defined process that is transparent where there are checks and balances or you have outside consultation to really evaluate what it is that is right at the time for science. The IOM recommended that some process be implemented to do that.

MR. WAXMAN. They also recommended that it be a recommendation to Congress from the NIH, not that NIH act unilaterally.

DR. ZERHOUNI. There are two levels of organization you need to consider. One is, within an institute, it is important to leave the institute directors with the ability to change things within institutes, according to

what their sense of mission is and what the strategic plan is. I don't think that is an issue.

What you are referring to is creation or removal of institutes that are specially authorized. I think it would be quite unusual for an NIH director to do that single-handedly. I don't think that has been used in the past simply because these institutes have been created by Congress, in most cases.

So I think the key here is not to have more authority. The key here is to have the discipline of looking at structure so that it doesn't become fossilized.

So whatever process is found--I mean, I don't have a hunger for that authority. I just want the right thing to be done for NIH.

You will hear from previous directors and current members of the scientific community that there are institutes that are converging so much that perhaps different ways of integrating them might be a good idea. Do I want this unilateral authority? No. I don't think that is survivable, given the fact that over the past year any suggestion for change will be resisted, unless it is done through a process where there is consensus to be achieved. So my goal is not to create any new authority except those that are in law.

CHAIRMAN BARTON. The gentleman's time has expired.

The gentleman from Georgia, Dr. Norwood.

MR. NORWOOD. Thank you very much, Mr. Chairman.

Dr. Zerhouni, I want to thank you for the job that you do.

DR. ZERHOUNI. Thank you.

MR. NORWOOD. You are a very fortunate man. You have a great job at a great institute, and the American people appreciate everything, I believe, that is happening over there.

This new bill seems to emphasize collaboration, which I think means when, in doing research, you might talk to your neighbor in another institute, if you are particularly working on the same thing, and it probably would be a good idea to share some of this together. Is that what you see collaboration as being?

DR. ZERHOUNI. Right. I think that is the idea, especially because--and it is necessary to have a balance between autonomy, because then you don't have a one-size-fits-all and you have different ideas. But it is also important to recognize the changes that are occurring in science and public health, and that is why I think pushing towards collaboration is a good direction.

MR. NORWOOD. Well, the bill seems to imply that if institutes collaborate there is potentially additional funds from the general fund if you do that well.

Collaboration, it would seem to me, might mean more than just sharing money, but it also might seem to me to be sharing ideas and research efforts together. Am I on the right track?

DR. ZERHOUNI. You are absolutely on the right track. That is the intent I think of the committee's language today where the division of portfolio analysis and strategic coordination is proposed. I think that is the instrument that you need. You need an intelligent function that looks across on a regular basis across all mission areas of the NIH. That is point number one.

Point number two, as you know, institutes have their budgets; and, in the past, it was very hard--if you had an initiative, unless the institutes came together, it was very hard to commingle funds and go after that initiative together. This will allow you to do that, for a small percentage of the NIH budget, not a large percentage. So that gives us more flexibility and gives us the ability to be responsive.

MR. NORWOOD. Well, just to be clear for the record and for my own personal satisfaction, let's say, for example, that the Dental Institute is doing stem cell research on baby teeth, but down the hall another institute also is doing stem cell research, and these two institutes are talking to each other, working together, trying to help each other but are not necessarily sharing any funds to do that. Under this bill, would that be collaboration?

DR. ZERHOUNI. No, this is actually something that happens now, where institutes may in fact work in areas of science and spend their own funds for their own scientists, and they coordinate without commingling funds.

What the Common Fund will do is will allow NIH to be responsive to new areas of science, things that are unproven, things that institutes on their own cannot do by themselves. So it is really a Common Fund for shared needs, not just between two institutes. It is really for all of NIH.

MR. NORWOOD. But it doesn't necessarily depend on getting into--that general fund doesn't necessarily depend on just sharing funds.

DR. ZERHOUNI. That is right.

MR. NORWOOD. Quickly, because I need to get in another question, a lot has been said here today about health disparities. I was an original sponsor of the legislation that created the National Center for Minority Health and Health Disparities at NIH, and I had the honor of managing that bill when we passed it on the floor. Would you agree that health disparities remain a major problem for our healthcare delivery system today?

DR. ZERHOUNI. I agree.

MR. NORWOOD. And would you agree that the National Center for Minority Health and Health Disparities plays an important role in addressing these problems?

DR. ZERHOUNI. It does play an important role. I just want to make sure, also, that we shouldn't let the other institutes think that because there is SCM they do not have the responsibility. So it is the responsibility of the entire NIH.

MR. NORWOOD. Understood.

Finally, this bill gives you a lot of new authority and that, I trust, you will use wisely and responsibly, I am sort of--that is a given in my mind. But would you state for the record that you will continue to work to eliminate health disparities by working with the Center and in fact with all of NIH?

DR. ZERHOUNI. As you know, the Center has a special legislation that obligates us to do that, so we absolutely will. First of all, without legislation we would do it; and in the current legislation we do it.

MR. NORWOOD. Thank you very much, Doctor, Mr. Chairman.

CHAIRMAN BARTON. Mr. Rush. And Mr. Norwood, could you come Chair for a while?

MR. NORWOOD. I can't. I would love to, but I have got to see an all-powerful senator.

CHAIRMAN BARTON. Mr. Shimkus, can you come Chair then? Mr. Rush, you are recognized for 5 minutes.

MR. RUSH. Thank you, Mr. Chairman.

Dr. Zerhouni, how do you think the committee print before us today addresses what you refer to in your budget to eliminate--to reduce and eliminate health disparities 2002 to 2006? How does this current committee print--how does it help us to address this foremost issue in your own words?

DR. ZERHOUNI. I am sorry, I missed the beginning of your question. Are you referring to the bill?

MR. RUSH. Yes. How does the bill--the committee print that is before us, that will be before us tomorrow, how does it address the, quote, "foremost health challenge," which is disparities among minorities?

DR. ZERHOUNI. I think it does not address it specifically, nor does it address specific health issues across NIH. The purpose of this fund is to assemble scientists and public stakeholders on a regular basis to, in fact, make the case, if there is a strong case, to say we need more effort here or we are overlapping there, we are inefficient over there. That is the purpose of this bill, is better coordination, better understanding of, in this case, health disparities. What is the portfolio across NIH? How can we enhance that? Do we need to put in Common Fund resources there now?

Is it a priority, remembering that that is a small percentage of the total budget?

MR. RUSH. The Center for Minority Health and Health Disparities, that Center operates as a one-stop--does this center have any kind of authority that will spread throughout NIH in terms of other disparate minority health initiatives? Is this Center a clearinghouse, used as a clearinghouse?

DR. ZERHOUNI. As you know, the Center has the responsibility of coming up with the NIH strategic plan for Minority and Health Disparities, so on a regular basis it convenes all the other institutes. So the authority to do that also accounts for--

MR. RUSH. What about enforcement? Does it have any enforcement mechanisms?

DR. ZERHOUNI. Through the reforming mechanism, it accounts, obviously, tracking for the strategic plan, stimulating the collaboration with the other institutes. Each institute has in itself a responsibility for minority health and health disparities because I think you want every institute to be committed to it.

MR. RUSH. Okay. Does the Center on Minority Health and Health Disparities have any oversight authority over the private research universities and organizations? Does it have any authority over them?

DR. ZERHOUNI. I believe so. Through any granting mechanism they have no authority, but they have, obviously, the relationship of a Federal agency through a private institution, yes.

MR. RUSH. And do you have--have you had any instances where you have had to utilize that authority at all as it relates to private institutions, universities and colleges as it relates to their minority--health disparities as it relates to--

DR. ZERHOUNI. Right. Well, as you know, the Center has special authorities to support Title 736 institutions and has done so in supporting what you would call seed infrastructure funding and supporting the endowment of these institutions, so there is a large program within, which is about a third of the budget, that supports specifically such institutions.

MR. RUSH. So are you saying then that the Center can verify to this committee that all of the clinical trials conducted by these private entities, that they have no disparity issues related?

DR. ZERHOUNI. Oh, that authority--okay. I think you are asking me whether or not the health disparities--the Center has enforcement authority over compliance with health disparities recruitment. For example, minority health--recruitment of minorities in trial, that I don't think exists as an authority of the Center.



But across NIH we have policies related to fair representation across all trials, across all institutes for that, and we ask every institution and every clinical trial to report on a specific basis participation from minority and underserved populations. But it is not a specific authority of the Center. It is a general authority of the--it is the general requirement of the NIH.

MR. SHIMKUS. [Presiding.] The gentleman's time is expired, and I will recognize myself for 5 minutes. I just have two quick questions, Dr. Zerhouni.

As you know, back in 2002, I was a sponsor of legislation that codified the Office of Rare Diseases at NIH. What plans does the NIH have to advance the study of rare diseases? Which is a problem. Because it is rare, the ability of the folks who would then get a return on the investment based upon medical research is a hard case to make. So that is where we got involved and appreciate what has been done; and the concern is, in this reorganization restructuring, what is going to happen to the rare disease?

DR. ZERHOUNI. The authorities of the office will not be changed at all. I think these offices play an important role in understanding the specific issues that relate to their mission--in this case, rare diseases.

As you know, there are hundreds of rare diseases; and, therefore, their scope is quite large. So we need to preserve, in fact, the ability of this office to continue to issue strategic plans, issue priorities, coordinate with other agencies as it has in the past. So our vision is that those should remain intact, authorities and visions should remain intact.

MR. SHIMKUS. Thank you.

My final question is, we have had numerous hearings on NIH over the years, and sometimes as members of the full committee--and, really, the subcommittee has a better handle on what you do and how you do it and where you do it. Sometimes the public as a whole stirs things up, sometimes beneficially and things that we think are good. So the question is, part of this reform as to how do we get better information out in the public domain so they really understand how you work, how you choose priorities, where the money goes to, where are the results--so how do you perceive us getting information out in the public domain which the public at large would have a better chance of understanding?

DR. ZERHOUNI. I think transparency is very important. I think we have tried to the greatest extent possible. What we find is that sometimes it is difficult to classify what you are doing specifically for one disease, one purpose because, as I give the example pediatric cancer, is it pediatrics or is it cancer? So we want to increase the transparency by creating a common language, a common standard and using technologies

that we call knowledge management that will allow to look at the portfolio in many different ways.

What is really obvious is that to create transparency you need to facilitate access to the information and have a common standard across all institutes, and I think that is what this bill will do, in addition to the coordination function in the coming--the functional integration that we talked about.

MR. SHIMKUS. Great. That is all the questions I have, so I will yield back my time.

Now I would like to recognize my friend from Michigan, Mr. Stupak.

MR. STUPAK. Thank you.

Dr. Zerhouni, as I mentioned in my opening statement, the Oversight and Investigation Subcommittee, we have been holding hearings on Dr. Trey Sunderland and Dr. Thomas Walsh and their misdealings as NIH scientists. These scientists are still currently conducting research at NIH, despite their ethical and possibly illegal wrongdoings.

At last week's hearing, Dr. Kington claimed NIH did not have the authority to take disciplinary action against these two individuals because they were members of the Commissioned Corps. I have since learned that, according to the Public Health Service Manual, PHS commissioned officers are subject to involuntary transfer or involuntary reassignment at any time to meet the needs of the organizational component; and in this case it would be NIH. So, as I read this, it seems to me NIH can demand that these two employees be re-assigned, transferred. So I am completely at a loss as to why NIH has not done that.

DR. ZERHOUNI. I am not aware of that specific authority to the NIH. It might be an authority of the Public Health Service--

MR. STUPAK. Public Health Service, which says--I am quoting--Public Health Service commissioned officers are subject to involuntary transfer or involuntary reassignment at any time to meet the needs of the organizational component, end of quote. And organizational component in this case would be NIH, would it not?

DR. ZERHOUNI. To serve the needs of the organizational component. Because, as you know, the Public Health Service Corps is under the Surgeon General and the Assistant Secretary for Health. I think in this particular case what is really important is we are not talking about a functional reassignment, this is a disciplinary process where we--

MR. STUPAK. What is the difference? I mean, if you can re-assign a person if they have serious ethical violations and possible criminal violations, why would you keep them at NIH doing research? Why

wouldn't you re-assign them and get them out of there? Doesn't that send a bad signal to everybody else at NIH?

DR. ZERHOUNI. First of all, I think that, in this particular case, I would like for the record--because I have heard some comments--for the members of the committee to also take notice that every event that you are referring to occurred many years ago, several years ago; and the new rules that NIH has implemented in the ethics domain are the most stringent rules that have been created by any agency, including the total ban on interactions and conflict between our scientists and industry. That is--I hope that is recognized as the degree of seriousness--

MR. STUPAK. That may be so, but it is hard for us to believe that when you still have these people working for you.

DR. ZERHOUNI. No, sir. We have two people at NIH, and I think the due process for these two depends not on the NIH as you have heard but on the Public Health Service Corps. And if the interpretation is different, I am absolutely more than happy to look at it.

MR. STUPAK. Did they receive a \$50,000 retention bonus from your agency?

DR. ZERHOUNI. That I think is not a good decision. I was not aware--

MR. STUPAK. Well, did they receive a \$50,000 retention bonus? I am sorry, \$15,000?

DR. ZERHOUNI. I am not sure of that, and I will--

MR. STUPAK. I will tell you what. I will follow those up in writing.

Let me ask you this question: At the last hearing we had on the NIH draft bill, I spoke about the importance of pediatric drug studies that NIH is tasked with doing, because the drug companies are not doing it. It is important that these studies are done. Because, as you know, drugs are typically approved by the FDA for adults, and drugs are widely used in pediatric patients without any efficacy or safety information specific to the pediatric population. In fact, only about 25 percent of the drugs in the U.S. today have been studied and labeled for pediatric patients.

Since 2003, NIH has been required to assemble a list of drugs for which pediatric studies are needed. There are currently 51 drugs on this list. Only nine have efforts under way to begin designing or conducting these studies. No drug has been removed from this list because of a completed study. It shows that this program isn't working as well as Congress intended, so I would like to hear your views on it.

I would also like to point out that this program was created in response to efforts by myself and others to strengthen the authority of the FDA to require drug companies to do pediatric studies. Given the poor performance of this program, I think we need to revisit the authority of the FDA to require drug companies to do pediatric studies. So what

recommendations do you have on how we can best move forward with pediatric studies, and what enforcement do we have to make companies-- we have 51 of them, only nine have been done, how do we get them to do these studies? What recommendation would have you for us?

DR. ZERHOUNI. Well, first of all, I have to agree with your interest and concern about the fact that pediatric drugs need to be tested in pediatric patients. We have spent approximately \$25 million in 2005, and the same in 2006, to test the drugs that were on the list that you mentioned, nine out of the 51. These research protocols in children are much more difficult than they are to conduct in adults. They need to be thoughtfully evaluated, and it takes more than 2 years to basically do a trial. So I think that to say that the program is not responding is a little premature. I think we need to really give it a little more time to see if these trials are providing that answer.

Now there is an issue that you may want to consider, and that is that off-patented and unpatented drugs are a different issue in terms of pediatric trials, and that could be a clarification that would be right helpful to the field. The role of the foundation for NIH obviously, in terms of supporting these trials, that needs to also be, perhaps, enhanced and clarified in terms of how do you fund these trials. These trials are very expensive. Research in children is, by definition, much more difficult to do; and we need to just continue the effort. But you have my agreement on this one in terms of finding better ways to test all these drugs as fast as we can.

MR. SHIMKUS. The gentleman's time is expired.

MR. STUPAK. Mr. Chairman, I think we are going to have further time to follow up with written questions?

MR. SHIMKUS. Yes, if you hang around.

Just for point of clarification that staff counsel has advised me on is these retention bonuses were denied by the Public Health Service Corps Commission, so there was a process by which they didn't receive the bonus commissions.

So, with that, I would like to recognize Dr. Burgess for his round of questions.

MR. BURGESS. Thank you, Mr. Chairman.

Dr. Zerhouni, good to see you again. I apologize for not being here during the earlier part of the questioning, so if I ask things that have already been asked, I apologize, but it won't hurt to hear them again.

I will ask the question that Chairman Barton asked of the other panel, and since I wasn't here to hear your response, is this good legislation that we have before us?

DR. ZERHOUNI. Well, as you know, as a member of the executive branch, I can't comment on legislation.

What I said was, during my opening statement, is the fact that finding better ways of performing collaborative science in a time when sciences converge and public health issues are really seen across categories of patients where patients themselves suffer from several diseases at once, better ways of integrating the function of a complex organization like NIH are welcome, and I think this bill is going in that direction, and we believe that this is the right direction to go to.

MR. BURGESS. We heard some comments during the opening statements about the funding levels. Can you elaborate a little bit on the funding levels as proposed in this authorization bill? Do you see them as adequate for the NIH to be able to perform its mission?

DR. ZERHOUNI. I don't know what the comments were. Were they not enough or too much?

MR. BURGESS. Well, on this side, it was too much; and, that side, it was not enough.

DR. ZERHOUNI. Well, you are putting me in a difficult position. Because as the Director of an agency that sees the challenges ahead of us, with 6,600 diseases and conditions and new fields of research, I pointed out that this year NIH is going to receive twice as many applications for research from twice as many scientists almost, and each grant is more expensive by 30 or 40 percent, so any help we can get is welcome.

MR. BURGESS. Well, Dr. Miller, I think, in his statement alluded to the young and aggressive scientist--and I didn't realize that you don't come up with a Nobel-Prize-worthy thought after 40. That was a little intimidating when I heard that. But, at any rate, he said it was important to capture these young scientists while their enthusiasm burned brightest. Are you going to have the tools that you need with this authorization bill to do that?

DR. ZERHOUNI. Yes, I think so. It would be very helpful to have the ability to move funds towards areas of priority such as, for example, the development of the pipeline of talent that we need to maintain our competitiveness in the future. And I think if Dr. Miller said that, I fully endorse that. My main concern is new investigators, new ideas and making sure that we have the Nobel Prizes of the future in this country.

MR. BURGESS. Yes, sir.

On the issue of the disparity issue that has been talked about at some length, I know when I visited Dr. Eschenbach at the National Cancer Institute, for example, he gave me a publication that the NCI has put out about making healthcare disparities disappear, which is part of the National Cancer Institute's mission. I am assuming that the other institutes have similar work that they do on health care disparities as

well, that that is an ongoing process and not purely consigned to the one institute that is involved with studying disparities.

DR. ZERHOUNI. Right. Actually, every institute has a program and has a focus on health disparities across the entire portfolio, but the National Center for Minority Health and Health Disparities really keeps track of that and initiates the strategic plan which is reviewed and submitted to Congress.

So I think every institute is and should be concerned and committed to alleviate this issue, which is in the top five priorities of the NIH, from my standpoint.

MR. BURGESS. How often are those reports issued?

DR. ZERHOUNI. I believe the strategic plan and the report is a yearly progress report, and the strategic plan, if I am not--I don't know the details, but it should be renewed every 2 to 3 years.

MR. BURGESS. Mr. Chairman, I don't know if it is possible that the committee staff could make that available to Members of Congress, but I think that would be very helpful.

Mr. Stupak's question about the--to which you replied that there was a total ban on outside influence with NIH researchers, which I appreciate as something that you thought was necessary at the time, but it also concerns me that, as we talk about these bright young researchers and wanting to have access to the best and the brightest, that having this total ban on outside activities is perhaps pernicious to recruiting the best and the brightest. A system that would allow that but would have complete transparency so everything is reportable and above board and everyone knows about it would seem to be more satisfactory. Is there any chance we can move to a system like that?

DR. ZERHOUNI. Right. I think you are referring to one of probably the most difficult decisions we have had ever had to make. The issue was very simply, in my view, that it was very important to establish a system where you could oversee these activities, but, in the meantime, you really couldn't afford to have what we call outside activities. These are the private activities of scientists with industry.

We do not want to stop the interaction when it is a positive interaction that helps the public good; and, really, how you draw the line is that we are encouraging official activities through the--and without payment on the side. Currently, we want our scientists to interact with industry.

However, I have the same concern you have; and that is that, over a long period of time, do you really impoverish the environment for the scientists at NIH? I have to say this is one of the most difficult issues that we have to deal with. So we put a study period of 1 year, and we are going to evaluate the impact this has on the quality of our science, our

retention, recruitment and all of that. As we do, as obviously we have shown before, we will evaluate the impact and perhaps look at different ways of implementing what I think you want, and that is an agency that you can trust, that the advice of which is unimpeachable.

MR. SHIMKUS. The gentleman's time is expired.

The Chair recognizes the gentleman from Pennsylvania, Mr. Doyle.

MR. DOYLE. Thank you.

Dr. Zerhouni, welcome, and thank you for being here today.

I want to start by commending your leadership in developing and implementing the NIH's public access policy, the first of its kind in any Federal agency. Public access to taxpayer-funded research in my view is an extremely important tool that NIH can use to better manage its research portfolio while delivering all its benefits to the research community and the public.

When you unveiled NIH's policy in Access Policy in February of 2005, you said, and I quote, we are saying that scientists should release their findings as soon as possible for the benefit of the public. After all, the public paid for them. With less than 4 percent of the original manuscripts being deposited in PubMed Central under the policy, it seems clear to me that this aspect of the policy isn't working as well as we all hoped it would.

I agree with the comments you made earlier this year, that the current policy's voluntary nature is not providing an adequate incentive for investigators to comply. What specific actions can NIH take to increase the participation rate?

DR. ZERHOUNI. Well, as you know, what I tried to do was to, initially, move the ball forward. Because when I looked at that issue, nothing really happened. So we need to really start somewhere.

And the two things we did was say, okay, let's start voluntary, since a lot of people said this is a good thing, and let's put an oversight mechanism to see that the policy addresses some of the concerns that were there before the policy was implemented, that it would be very costly, that we couldn't deliver the product, if you will, and so on. So we needed to have a phase of evaluation in a dynamic process by which we could then readjust the policy.

As you said, the voluntary component, for whatever reason, is at 4 or 5 percent right now; and that is not enough. From my standpoint, we need to have a full database of what is being produced through funding by NIH. I need to be able to exploit that for portfolio management, for reporting to Congress was mentioned just a few seconds ago, and, third, I think, at a reasonable time, the public should have access to what it pays for.

Even though I recognize completely the important contributions of publishers and scientific societies to the peer review process, I believe it is very important not to damage that component. So we need to find a sweet spot here; and I have asked our staff to, in fact, look at all aspects and all options of this policy as we speak--I am going to have meetings with them very soon--and to evaluate, in fact, what components of the policy need to be modified.

MR. DOYLE. I see that both the Public Access Working Group and the National Library Medicine Board of Regents have recommended that NIH revise the existing public access policy so that it is made mandatory and require articles to be submitted within 6 months of publication to a journal.

What is your take on that recommendation, and do you intend to implement any of these recommendations? Or, if not, what revisions to these recommendations--

DR. ZERHOUNI. That is an excellent point. Obviously, if you get a recommendation like that, you don't understand if it was unanimous or not. It wasn't, and it was basically a divided recommendation, although the majority was obviously behind the recommendation that you just described, a mandatory 6 months.

I believe that we need to evaluate what the next steps are going to be in this policy by looking at both sides of the issue and try to find a sweet spot where we can, in fact, make sure that both mandatory incentives are there, if needed, or positive incentives are there, if needed, to achieve the goals that I initiated. But I can say that I don't think we should do it at the expense of damaging scientific societies.

For example, one of the societies that strongly opposes the policy we have taken is the Federation of Experimental Biology Society, and I need to be sensitive to that. So, obviously, it is like a jury. If everybody was on the same page, I would have moved already.

MR. DOYLE. Sure. And nobody wants to put the publishers--this isn't about trying to impact them negatively.

You know, one of the charges we are getting from some of the associations and some of the publishers is there has been no hearings on NIH's public access policy. As a final question, before you implemented the current policy, what steps did your agency take to listen to the scientific community, the publishers and the public?

DR. ZERHOUNI. Sir, we had, if I recall, three meetings where we had stakeholders come, scientific community, publishers, societies, librarians, and heard about all of them. Obviously, we also had a rulemaking process where we received public comments. We had administration meetings within the Administration. We had, obviously,



input from Congress, both sides of--I mean, the Senate and the House, both sides of the aisle. All of that was occurring at the time.

MR. DOYLE. Thank you very much. I look forward to working with you to make this policy even better.

DR. ZERHOUNI. Thank you.

MR. SHIMKUS. The gentleman's time is expired.

The Chair wants to ask unanimous consent that those members wishing to submit questions to return in writing will have the appropriate amount of days in which to do that. Is there objection? Hearing none, so ordered.

The Chair recognizes the gentleman from Michigan, Mr. Rogers.

MR. ROGERS. Doctor, thank you for your patience today and for being here in front of the committee and committing so much time.

You and I have had discussions not only here but outside of the committee on pain care and pain care management. I want to applaud you. I think you have taken--we have come a long way since I got here in 2001 in our discussions on pain care and how we treat it both in research and development and education and access.

In this bill, there is a requirement that a summary of the research activities throughout the agencies include pain care and palliative care. Give me your opinion. Where do you think that takes NIH and where that allows us to go when we talk about pain care management in the United States?

DR. ZERHOUNI. As you know, my feeling is that this is a very critical issue not just in the delivery of healthcare, but it is also a critical research issue that needs to be worked out across all institutes and across all diseases, as you well know; and I think the consortium on pain is doing a great job under the leadership of Dr. Tabac, and the funding shows it. Even though the budget has been pretty much flat over the past 3 years, since the end of the doubling in 2006, funding for pain research went up almost by 20 percent. So there is a realization that this needs to be done.

Integrating pain and pain issues in every disease is an important goal, so I am in favor of having that being a permanent component of reporting, if I understand your question.

MR. ROGERS. Yes, when we got here, it was less than 1 percent of NIH budget was dedicated to pain. And when you look at how that cross-sections every disease--cancer, AIDS, arthritis, you name it--it is a component of what brings that patient to that physician or that care provider.

We still to this day, even though funding has gone up, have very little understanding--and I agree with you, on the research--in education even when it comes on behalf of physicians. And one of the things that

concerns me today is now it has become a little more chic, pain care management. There are shingles going up all across America, and there is not a very good understanding, I don't believe, because there is no coordinated way to find out what is the best practice in pain care management for ailment A or B or C.

What we are finding is these doctors have set up their own networks trying to understand it, doing their own networking across the country, probably not the best practice for something we know impacts so many Americans and so many Americans to the point that it has really taken away their quality of life almost completely. So I am very eager to see this pass and very eager to continue to work with you.

You know, I always say it is lend me your ear and we can solve the pain problem, education, access and research. I think we are still behind. I am not as convinced as you are on the consortium's ability to impact it. I do believe we need to heighten that awareness and continue that cross-section for research, and I look forward to working with you. Especially when this comes out and you have highlighted, I think this is going to be important for us all, I think. And I hope you are watching all those shingles going up around the country.

DR. ZERHOUNI. Right. Exactly. And it is quite a process that is ongoing right now. So that is why I think we have an interest in making sure that that is represented in our analysis. This is one of the reasons why I think the legislation proposing a division of portfolio analysis and strategic initiatives is important. Because then you have an explicit, non-special-interest-driven process that allows you to address questions like what you are referring to.

MR. ROGERS. Doctor, thank you very much.

DR. ZERHOUNI. Thank you very much.

MR. ROGERS. I yield back.

MR. SHIMKUS. The gentleman yields back his time.

I want to thank you, Dr. Zerhouni.

I want to make an announcement. The markup of this bill will be tomorrow at 10 a.m. It will be followed by an assortment of other bills. Members should be prepared to be here late tomorrow night.

I want to thank you for your time. I think everybody is really excited about moving forward.

With that, I am going to adjourn this hearing.

[Whereupon, at 4:58 p.m., the committee was adjourned.]

